

EPA Reg. No. 2596-166

November 22, 2011

Document Processing Desk
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: Mr. Richard Gebken (PM # 10)

RE: HARTZ REF #128, EPA Reg. No. 2596-RAG-163
HARTZ REF #129, EPA Reg. No. 2596-RAU-164
HARTZ REF #130, EPA Reg. No. 2596-RAL-165
HARTZ REF #131, EPA Reg. No. 2596-RAI-168

SUBMISSION OF REVISED DATA MATRICES

Dear Mr. Gebken:

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688 is submitting revised Data Matrices for the above listed products. These revisions incorporate all comments provided in the DER's completed in late July and early August of 2011. Requested changes to MRID's are reflected here.

The Agency will now be able to conclude their reviews and assign the proper label text categorizations for the products. Additionally, MRID numbers have been included for all Product Chemistry citations made on behalf of these 4 registrations

If you have any questions or need any additional information, please feel free to call me at (201) 271-4800, ext. 7202 or <mailto:robert.rosenwasser@hartz.com>.

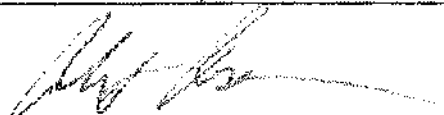
Sincerely yours,


Robert Rosenwasser
Regulatory Affairs Agent

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director, OPPE Information Management Division (2137) U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

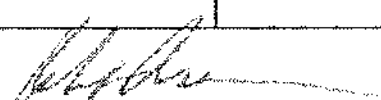
DATA MATRIX

Date November 22, 2011			EPA Reg. No./File Symbol 2596-RAA		Page 1 of 2
Applicant's/Registrant's Name & Address: Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094			Product Hartz Reference #131		
Ingredient Fipronil/(S)-Methoprene					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830-1550	Product identification and composition	48379002	Hartz	Own	
830-1600	Beginning materials	48379002	Hartz	Own	
830-1650	Description of formulation process	48379002	Hartz	Own	
830-1670	Formation of impurities	48379002	Hartz	Own	
830-1750	Certified limits	V	Hartz	Own	
830-1800	Enforcement analytical method	48379003	Hartz	Own	
830-6302	Color	48379001	Hartz	Own	Self-certification
830-6303	Physical state	48379001	Hartz	Own	
830-6304	Odor	48379001	Hartz	Own	Self-certification
830-6314	Oxidation/Reduction	Waiver	Hartz	Own	Self-certification
830-6315	Flammability	483792001	Hartz	Own	Self-certification
830-6316	Explosibility	Waiver	End use product is not potentially explosive.		
830-6317	Storage stability	To be submitted	Hartz	Own	In progress
Signature 			Name and Title Robert Rosenwasser Regulatory Affairs Agent		Date November 22, 2011

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date November 22, 2011			EPA Reg. No./File Symbol 2596-RAA		Page 2 of 2
Applicant's/Registrant's Name & Address : Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094			Product Hartz Reference #131		
Ingredient Fipronil/(S)-Methoprene					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830-6320	Corrosion characteristics	To be submitted	Hartz	Own	In progress
830-6321	Dielectric breakdown voltage	Waiver	End use product is not to be used around electrical equipment.		
830-7000	pH	Waiver	End use product is not to be dispersed with water.		
830-7100	Viscosity	48379001	Hartz	Own	Self-certification
870-1100	Acute oral toxicity	43951703	Merial		
870-1200	Acute dermal toxicity	43577706	Merial		
870-2400	Acute eye irritation	44942006	Meria		
870-1300	Acute inhalation toxicity	Waiver	Merial		
870-2600	Acute dermal irritation	44942007	Merial		
870-2600	Skin sensitization	44942008	Merial		
810.3300	Product performance, efficacy	45618501, 45628101, 45628102, 45628103, 45628104, 46019201, 46019202	Merial		
870.7200	Domestic Animal Safety	43863801, 44942009	Merial		
Signature 			Name and Title Robert Rosenwasser Regulatory Affairs Agent		Date November 22, 2011

FAST-TRACK AMENDMENTS-Completeness Screening Checklist

Experts In-Processing Signature: Debrale 5/4/11EPA Reg. Number: 2596 - RABEPA Receipt Date: 5/2/11

	Check List Item	Yes	No	NA
1	Application Form (EPA Form 8570-1) - signed?	✓		
2	Confidential Statement of Formula (EPA Form 8570-29) - signed?	✓		
3	Certification with Respect to Citation of Data (EPA Form 8570-34) signed?			
4	Formulator's Exemption Statement (EPA Form 8570-27) - signed?			
5	Data Matrix (EPA Form 8570-35) [Applicable, for adding me-too uses]			
	a) Selective Method?			
	b) Cite-All Method? Applicant owns data or list only the companies offered to pay			
	c) Public copy of Matrix provided? See PR Notice 98-5			
6	Is Label Included? (5 copies)			
	Comments:			
	<p><u>This appears to be a CF resubmission to a currently pending R272 PRA action.</u></p> <p><u>no</u></p> <p><u>next review needed.</u></p> <p><u>I need approved</u></p>			

S: 894962

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Pending Product Amendment

Billable: ☐ Yes ☒ No

Company: 2596 THE HARTZ MOUNTAIN CORP

V

Print Letter

Enter More Information

Tracking

Risk Manager: Registration Division, Risk Management Team 10

Product #: 2596-RAA Product Name: HARTZ REFERENCE #131

Override#:

Me Too:

Me Too:

Section3:

Product Name:

Application Date: 28-Apr-2011



OPP Rec'd Date: 02-May-2011



Receipt Content

Des

Front End Date: 02-May-2011



Risk Manager Send Date: 03-May-2011



CSF

FFS Due Date:

Negotiated Due Date:

OPP Target Date:



IP

Fast Track: ☐New Ingredient: ☐

View/Edit

Receipt Description:

CSF amendment

New Ingredient:

Request Date:

New Ingredient:

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Fee for Service

{894962H~

This package includes the following

☐ New Registration

☒ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: _____

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr. 10

Receipt No.

S- 894962

EPA File Symbol/Reg. No.

2596-RAA

Pin-Punch Date:

5/2/2011

☒ This item is NOT subject to FFS action.

Action Code:

Requested:

Granted:

Amount Due: \$ _____

Parent/Child Decisions:

Inerts approved - J. Lock 5/5/11

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: *[Signature]* Date: 5-3-11

Remarks:

Resubmission??

Memorandum

Date: 2 / 15 / 11

To: PM 10, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☒ fully accepted submission
☐ partially accepted submission
☐ rejected submission

To the Document Center (ITRMD)

*Please transfer jacket/mini-jacket to the Product Manager Team circled below:

Minor Use Section: **PM -5**

Insecticide Branch: **PM -10** **PM-13**

Herbicide Branch: **PM-23** **PM-25**


Fungicide Branch: **PM-20** **PM-21** **PM-22**

Insect/Rodent Branch: **PM-1** **PM-7**

*Reminder to PM – If applicable, pick-up data from the Screening Room.

Processed by RD's Completeness Check Team


(Team Member Signature)


(Date)

Decision Seq: 445037	Action Code: R310.NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS) ...		
Tentative Start Date: 01-Mar-2011	Tentative Ind: Yes	FFS Original Decision: ...	
Tentative Due Date: 01-Sep-2011	75-Day Due Date: ...	FFS EUP Decision: ...	
OPP Target Due Dt: ...	21-Day Screen Dt: 01-Mar-2011	FFS Primary Decision: ...	
Negotiated Due Dt: ...	Start/Stop Clock: ...	FQPA Clock: ...	
Registrant: ...	Days Elapsed: ...		
Response Due Date: ...			

Decision Status

Tracking

Create Resubmission

FFS Letters

FFS Information

Action Code History

Secondary Decision

Current Status: PENDING (10 Feb-2011)

Decision Comments	Payment	Unmatched Payments	75 Day Letters
Meetings & Milestones	FFS Information	FFS Negotiated Due Dates	OPP Target Due Date
Decision Ownership	Receipts	Data Package	Reduced Risk

Receipts	Staff Member	Reg/DCI Number	Submission Due Dt	Response
S 000997	Akintolotu, Bonaventure	2596-RAA	01 Sep-2011	PENDING

New Registration



21-Day Screen Completed by
Contractor

21-Day Expires on 3-1-11

Jacket # 2596 - RAA

MRID# 483792

Content Screen: Recommended to
Pass/Fail

86-5 Review: Passed/Failed/NA

Overall Status: Pass/Fail

Transfer This Jacket to:

Stephen Schaible

PM 10

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 02-08-11

Experts In-Processing Signature: Wilkins IK Date 02-11-11 Fee Paid: Yes

Division management contacted on issues No Yes Date

EPA Reg. Number: <u>2596-QAA</u>		EPA Receipt Date: <u>02-08-11</u>							
Items for Review			Yes	No	N/A*				
1	Application Form (EPA Form 8570-1)(link to form) signed & complete including package type		X						
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)		X						
	a) All inerts (link to http://www.epa.gov/oppr001/inerts/), including fragrances, approved for the proposed uses (see Footnote A)	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="text-align: center; padding: 2px;">yes</th> <th style="text-align: center; padding: 2px;">no</th> </tr> <tr> <td style="text-align: center; padding: 2px;">X</td> <td></td> </tr> </table>	yes	no	X				
yes	no								
X									
3	Certification with Respect to Citation of Data (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)		X						
	Certificate and data matrix consistent		X						
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="text-align: center; padding: 2px;">yes</th> <th style="text-align: center; padding: 2px;">no</th> </tr> <tr> <td></td> <td></td> </tr> </table>	yes	no					
yes	no								
	If applicable, is there a letter of Authorization for exclusive use only.								
4	Formulator's Exemption Statement (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)		X						
5	Data Matrix (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)		X						
	a) Selective Method (Fee category experts use)	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="text-align: center; padding: 2px;">yes</th> <th style="text-align: center; padding: 2px;">no</th> </tr> <tr> <td style="text-align: center; padding: 2px;">X</td> <td></td> </tr> </table>	yes	no	X				
yes	no								
X									
	b) Cite-All (Fee category experts use)	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="text-align: center; padding: 2px;">yes</th> <th style="text-align: center; padding: 2px;">no</th> </tr> <tr> <td></td> <td></td> </tr> </table>	yes	no					
yes	no								
	c) Applicant owns all data (Fee category experts use)	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="text-align: center; padding: 2px;">yes</th> <th style="text-align: center; padding: 2px;">no</th> </tr> <tr> <td></td> <td></td> </tr> </table>	yes	no					
yes	no								
6	5 Copies of Label (link to http://www.epa.gov/oppead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)		X						

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X		
8	Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)			/
9	If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)			/
10	Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

- * A.I. & % composition are available in OPP.
- * CSF is approved for non-food use
- * Data package is approved.
- * List of Completeness review deficiency
 - the extent of use data matrix + 8570-27 are missing
 - the method of data support selected on form 8570-34
- Registrant has resolved all issues stated above
- * Ticket is approved.

MRID: 483792

IK S-4813

* N/A - Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to <http://www.epa.gov/opprd001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/opppbd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/opprd001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

Fee for Service

{889997É~

This package includes the following

☒ New Registration

☐ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: _____

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr. 10

Receipt No.

S- 889997

EPA File Symbol/Reg. No.

2596-RAA

Pin-Punch Date:

2/8/2011

☐ This item is NOT subject to FFS action.

Action Code:

Requested:

R310

Granted:

R310

Amount Due: \$ 4807.00

Parent/Child Decisions:

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: *Amend*

Date: 2/10/11

Remarks:

Receipt for Section 3

S 889997

Resubmission: ☐ Yes ☒ No

Regulatory Type: **Product Registration - Section 3**

Fee For Service: ☒ Yes ☐ No

Application Type: **New Registration**

Billable: ☒ Yes ☐ No

Company: 2596 THE HARTZ MOUNTAIN CORP. **V**

Risk Manager: **Registration Division, Risk Management Team 10**

Product #: **2596-RAA** Product Name: **HARTZ REFERENCE #131**

Override#:

Me Too

Me Too

Section 3

Product Name:

Application Date: **04-Feb-2011**



OPP Rec'd Date: **08-Feb-2011**



Front End Date: **09-Feb-2011**



Risk Manager Send Date:



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

New registration

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Study

CSF

View/Edit

ISB'S Front-end PRIA Completeness Screen

Draft 3; 10/25/07

EPA Receipt Date: <u>2/8/11</u>		EPA Reg. Number: <u>2596-RAA</u>		
	Check List Item	Yes	No	N/A
1	Has the PRIA Fee been Paid ; is a copy of the check or Pay.gov receipt included in the Submission Package?	✓		
2	Is an Application Form (EPA Form 8570-1) Included in the Submission Package, is it completely filled out and signed including package type?	✓		
3	Is a Confidential Statement of Formula (EPA Form 8570-29) Included in the Submission Package, is it completely filled out and signed (boxes 1-21)?	✓		
4	Is a Formulator's Exemption Statement (EPA Form 8570-27) Included in the Submission Package?		✓	
5	Is a Certification with Respect to Citation of Data (EPA Form 8570-34) Included in the Submission Package?	✓		
6	Is a Data Matrix (EPA Form 8570-35) Included in the Submission Package?	✓		
7	Is a Label Included in the Submission Package?	✓		
8	Are Data Included in the Submission Package?	✓		
9	Is the Submission an Amendment?		✓	

Explore Registrations

Reg Number: 2596-RAA Reg. Type: Product Registration Section 3 Status: Under Review (09 Feb 2011)
 Name: HARTZ REFERENCE #131 <View Registration Details>

(New Receipts)

S	Submission Type	OPP Rec'd Date	Resubmission	Description
894962	Pending Product Amendment	02-May-2011	<input type="radio"/> Yes <input checked="" type="radio"/> No	CSF amendment
907709	New Registration	30-Nov-2011	<input checked="" type="radio"/> Yes <input type="radio"/> No	child resistant package testing
910180	New Registration	19-Jan-2012	<input checked="" type="radio"/> Yes <input type="radio"/> No	amended child resistant package testing

Decisions...

Data Requirements

D: Pending; 445037; 2596-RAA; R310; NEW PRO

75-Day Letters

ALERT S: 911979 18-Jan-2012; New Registration

S: 901779 6/14/2011; New Registration; 25%

S: 895591 5/2/2011; New Registration; 25%

S: 889997 2/8/2011; New Registration; 25%

ALERT

S: 911979 Reg #: 2596-RAA

Submission Type: New Registration

Resubmission? ☒ Yes ☐ No

E-Sub #

Decision #: 445037; R310; NEW PRODUCT; NON FAST TRACK (INCLUDES

Submitter Company: THE HARTZ MOUNTAIN CORPORATION

Application Date: 18-Jan-2012

OPP Received Date: 19-Jan-2012 Date Sent to Risk manager: 19-Jan-2012

Studies Included? ☐ Yes ☒ No

Fast Track? ☐ Yes ☒ No

Form A Signed? ☐ Yes ☐ No ☒ None

Date:

Form B Signed? ☐ Yes ☐ No ☒ None

Date:

Reviewer: Akinoboru Bonaventure

Received DT:

Editable Due DT:

Submission Due DT: 08-Mar-2012 Response: 19-Jan-2012

Priority Weight:

Priority Points:

Comments: Amended CRP package testing

Decision Information for 2596-RAA

Decision Seq: 445037	Action Code: R310, NEW PRODUCT, NON-FAST TRACK (INCLUDES REVIEWS O ...)			Decision Status
FFS Start Date: 08-Mar-2011	Tentative Ind: No	FFS Original Decision:		Tracking
Due Date: 08-Sep-2011	75-Day Due Date:	FFS EUP Decision:		Create Resubmission
OPP Target Due Dt:	21-Day Screen Dt: 08-Mar-2011	FFS Primary Decision:		FFS Letters
Negotiated Due Dt: 08-Mar-2012	Start/Stop Clock:	FGPA Clock:		Action Code History
Registrant Response Due Date:	Days Elapsed:			Secondary Decision
Current Status: PENDING (15-Jul-2011)				
Decision Comments	Payment	Unmatched Payments	75 Day Letters	
Meetings & Milestones	FFS Information	FFS Negotiated Due Dates	OPP Target Due Date	
Decision Ownership	Receipts	Data Package	Reduced Risk	

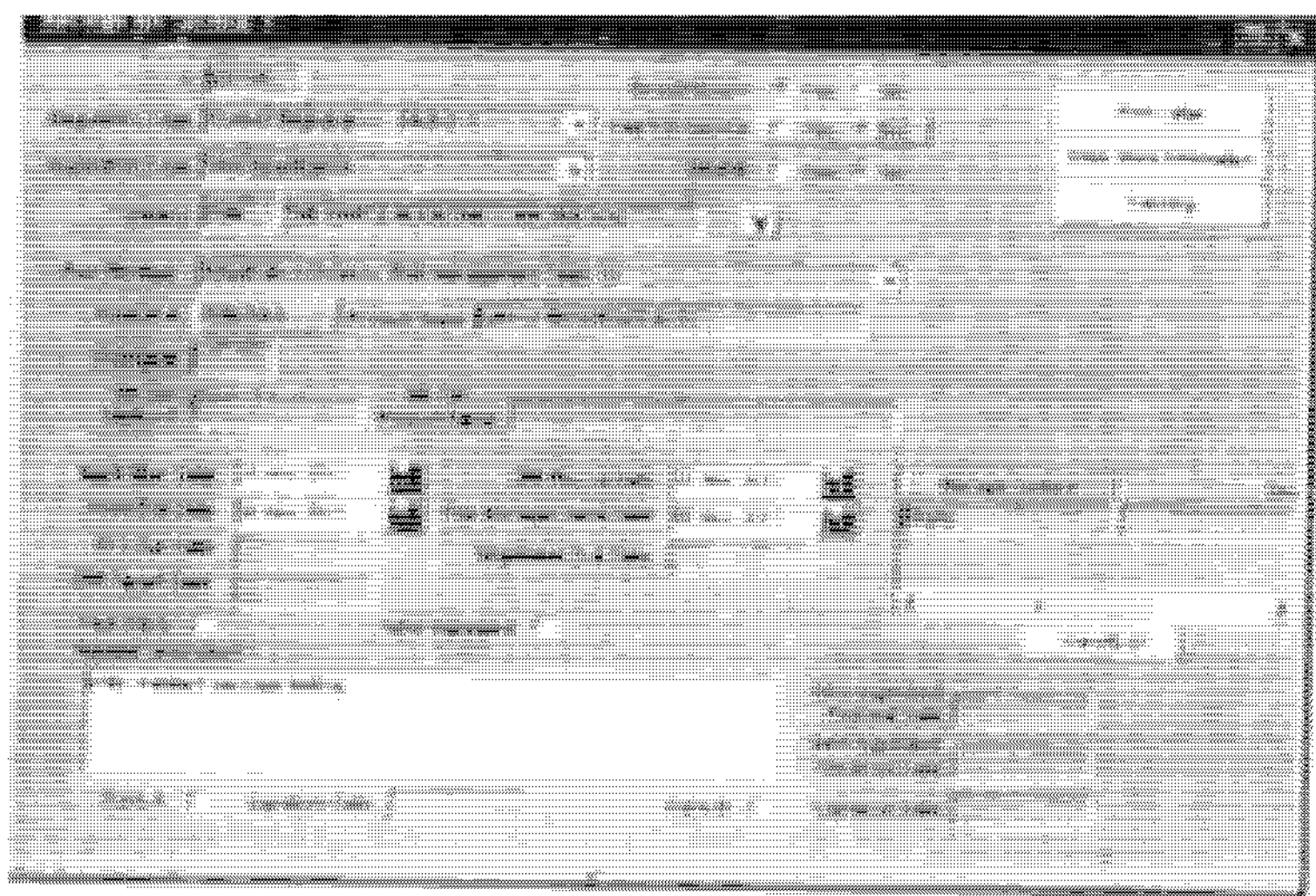
Receipts	Staff Member	Reg/DCI Number	Submission Due Dt	Response
S:811979	Akinlosotu, Bonaventure	2596-RAA	08-Mar-2012	PENDING
Amended CRP package testing				
S:901779	Akinlosotu, Bonaventure	2596-RAA	08-Mar-2012	GENERAL RESPONSE TO APPLI
Resubmission: Addendum to Existing Protocol for CRP				
S:895591	Akinlosotu, Bonaventure	2596-RAA	08-Mar-2012	PENDING
Resubmission to existing PRIA				
S:800007	Akinlosotu, Bonaventure	2596-RAA	08-Mar-2012	PENDING

Viewing Record 1 of 1

Review

2/21/2012

BAA





48684600

THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094-3688 • 201/271-4800

November 29, 2011

Document Processing Desk
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: **Mr. Richard Gebken (PM #10)**

**RE: HARTZ REF #128, EPA Reg. No. 2596-RAG
HARTZ REF #129, EPA Reg. No. 2596-RAU
HARTZ REF #130, EPA Reg. No. 2596-RAL
HARTZ REF #131, EPA Reg. No. 2596-RAA**

SUBMISSION OF CHILD RESISTANT PACKAGE TESTING

Dear Mr. Gebken,

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688 is submitting the Child Resistant Package Testing Reports for the above listed products. There are five reports (three copies of each), one covering each of the five dosages and we have also included a summary report for all five studies. The attached transmittal document identifies which studies support the above registrations.

The submission of these reports should complete the registration requirements for the above listed products.

If you have any questions or require additional information, please contact me at 201-271-4800, ext 7302 or smcnear@hartz.com.

Sincerely,

Sean McNear
Director Regulatory Affairs

Enclosure



THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094-3688 • 201/271-4800

CHILD RESISTANT PACKAGING CERTIFICATION STATEMENT
Title 40 part 157 subpart B

Registrant Name and Address:

The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094-3688

Products:

Hartz Reference # 128, EPA Reg. No. 2596-RAG
Hartz Reference # 129, EPA Reg. No. 2596-RAU
Hartz Reference # 130, EPA Reg. No. 2596-RAL
Hartz Reference # 131, EPA Reg. No. 2596-RAA

I certify that the packaging that will be used for the products listed above meet the standards of 40 CFR 157.32.

A handwritten signature in black ink, appearing to read "Sean McNear". The signature is fluid and cursive, written over a horizontal line.

Sean McNear
Director Regulatory Affairs

A handwritten date in black ink, "November 29, 2011", written over a horizontal line.

Date

TRANSMITTAL DOCUMENT

1. NAME AND ADDRESS OF SUBMITTER

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094

2. REGULATORY ACTION IN SUPPORT OF WHICH THESE PACKAGES ARE SUBMITTED

Submission of Child Resistant Packaging Testing Reports:

Fipronil; Hartz Reference #128, EPA File Symbol 2596-RAG

Fipronil; Hartz Reference #129, EPA File Symbol 2596-RAU

Fipronil and (S)-Methoprene; Hartz Reference #130, EPA File Symbol 2596-RAL

Fipronil and (S)-Methoprene; Hartz Reference #131, EPA File Symbol 2596-RAA

3. TRANSMITTAL DATE November 29, 2011

4. LIST OF SUBMITTED DOCUMENTS

3684601 VOLUME 1 Child Resistant Package Test Final Report (3 copies)
NCRT Job # 11-051
Fill Volume 0.5 mL

For Hartz Ref. # 129, EPA Reg. No. 2596-RAU
For Hartz Ref. # 131, EPA Reg. No. 2596-RAA

3684602 VOLUME 2 Child Resistant Package Test Final Report (3 copies)
NCRT Job # 11-052
Fill Volume 0.67 mL

For Hartz Ref. # 128, EPA Reg. No. 2596-RAG
For Hartz Ref. # 130, EPA Reg. No. 2596-RAL

3684603 VOLUME 3 Child Resistant Package Test Final Report (3 copies)
NCRT Job # 11-053
Fill Volume 1.34 mL

For Hartz Ref. # 128, EPA Reg. No. 2596-RAG
For Hartz Ref. # 130, EPA Reg. No. 2596-RAL

3684604 VOLUME 4 Child Resistant Package Test Final Report (3 copies)
NCRT Job # 11-060
Fill Volume 2.68 mL

For Hartz Ref. # 128, EPA Reg. No. 2596-RAG
For Hartz Ref. # 130, EPA Reg. No. 2596-RAL

8684605 VOLUME 5

Child Resistant Package Test Final Report
NCRT Job # 11-061
Fill Volume 4.02 mL

(3 copies)

For Hartz Ref. # 128, EPA Reg. No. 2596-RAG
For Hartz Ref. # 130, EPA Reg. No. 2596-RAL

8684606 VOLUME 6

Child Resistant Package Test Summary Report (3 copies)
Fill Volumes 0.5 mL; 0.67mL; 1.34 mL; 2.68 mL; 4.02 mL

For Hartz Ref. # 129, EPA Reg. No. 2596-RAU
For Hartz Ref. # 131, EPA Reg. No. 2596-RAA
For Hartz Ref. # 128, EPA Reg. No. 2596-RAG
For Hartz Ref. # 130, EPA Reg. No. 2596-RAL

VOLUME 7

Child Resistant Packaging Certification Statement (3 copies)

ADMIN

For Hartz Ref. # 129, EPA Reg. No. 2596-RAU
For Hartz Ref. # 131, EPA Reg. No. 2596-RAA
For Hartz Ref. # 128, EPA Reg. No. 2596-RAG
For Hartz Ref. # 130, EPA Reg. No. 2596-RAL

5. COMPANY OFFICIAL Sean McNear, Director Regulatory Affairs

6. SIGNATURE



7. PHONE

201-271-4800, ext. 7302



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

January 25, 2012

THE HARTZ MOUNTAIN CORPORATION
400 PLAZA DRIVE
SECAUCUS, NJ 07094

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 19-JAN-12. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094-3688 • 201/271-4800

January 18, 2012

Document Processing Desk
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: **Mr. Richard Gebken (PM #10)**

**RE: HARTZ REF #128, EPA Reg. No. 2596-RAG
HARTZ REF #129, EPA Reg. No. 2596-RAU
HARTZ REF #130, EPA Reg. No. 2596-RAL
HARTZ REF #131, EPA Reg. No. 2596-RAA**

**SUBMISSION OF AMENDED CHILD RESISTANT PACKAGE
TESTING**

Dear Mr. Gebken,

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688 is submitting the amended Child Resistant Package Testing Reports for the above listed products. There are five reports (three copies of each), one covering each of the five dosages and we have also included a summary report for all five studies. The attached transmittal document identifies which studies support the above registrations.

The reports were amended to address the deficiencies that were identified in the EPA letter dated December 16, 2011. We have added the Statement of Compliance with Good Laboratory Practices Standards and the Statement of Data Confidentiality Claims to all reports. I have also included copies of my original cover letter, the Child Resistant Packaging Certification Statement and the Transmittal Document (including the MRID numbers assigned by EPA).

If you have any questions or require additional information, please contact me at 201-271-4800, ext 7302 or smcnear@hartz.com.

Sincerely,

Sean McNear
Director Regulatory Affairs

Enclosure



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 16, 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

THE HARTZ MOUNTAIN CORPORATION
400 PLAZA DRIVE
SECAUCUS, NJ 07094

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 30-NOV-11. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

We are unable to accept your data submittal for further processing and review, because of the significant deficiencies noted below. It is being returned to you for correction. If deficiencies were found which apply to your overall submission, they are described immediately following this paragraph. If problems are found with individual studies, they are described below linked to the study identifier found on the enclosed copy of your bibliography.

48684601- 48684606

* You must include one of the two acceptable statements of data confidentiality claims under FIFRA section 10(d)(1)(A), (B), or (C) as the second element in each study. The language of two alternative forms of the Statement of Data Confidentiality Claims, shown in Attachment 3 of PR Notice 86-5, cannot be altered. See pages 8 and 13 of the Notice.

48684601- 48684605

* A statement of compliance or non-compliance with the Good Laboratory Practices Standards contained in 40CFR160 is required for all studies (except rangefinding studies and supplements to previously submitted studies) submitted to EPA. This statement must appear as page 3 of all studies, and must be signed and dated by the study sponsor, the study submitter, and the study director. Please see 40 CFR 160.12 for specific guidance.

Explore Registrations

Reg Number: 2596-RAA Reg. Type: Product Registration - Section 3 Status: Under Review (09-Feb-2011)
 Name: HARTZ REFERENCE #131 <View Registration Details>

(New Receipts)

S	Submission Type	OPP Rec'd Date	Resubmission	Description
894962	Pending Product Amendment	02-May-2011	<input type="radio"/> Yes <input checked="" type="radio"/> No	CSF amendment

Decisions...

Data Requirements

D: Pending; 445037; 2596-RAA; R310; NEW PRO

75-Day Letters

S: 895591; 2/2/2011; New Registration; 2596

S: 869997 2/9/2011; New Registration; 2596

S: 895591 Reg #: 2596-RAA

Submission Type: New Registration

Resubmission? ☒ Yes ☐ No

Decision #: 445037; R310; NEW PRODUCT; NON-FAST TRACK (INCLUDE)

Submitter Company: THE HARTZ MOUNTAIN CORP

Application Date: 28-Apr-2011

OPP Received Date: 02-May-2011 Date Sent to Risk manager: 03-May-2011

Studies Included? ☐ Yes ☒ No Fast Track? ☐ Yes ☒ No

Form A Signed? ☐ Yes ☐ No ☒ None Date:

Form B Signed? ☐ Yes ☐ No ☒ None Date:

Reviewer: Akinlosotu, Bonaventure

Received DT: Editable Due DT:

Submission Due DT: 08-Sep-2011 Response: 01-May-2011

Priority Weight: Priority Points:

Comments: Resubmission to existing PRIA

3/8/2012

P Chem: OK w/ comments. (See comments 2 & 7; pg 5)
 Tox/PL - Deficient (See comments 8, 9 on pg 3).
 Tox/CAS - Deficient (Comments 5, 6, 7; pg 2)
 DP 388644



Reg Number: 2596-RAA Reg Type: Product Registration - Section 2 Status: Under Review (08-Feb-2011)
Name: HARTZ REFERENCE #101 <View Registration Details>

(No New Receipts)

S	Submission Type	OPP Received Date	Resubmission	Description
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...Decisions...

- Data Requirements
- D: Pending; 445037; 2596-RAA; R310; NEW PRO
- 75-Day Letters
- S: 388997; 2/8/2011; New Registration; 259

S: 388997 Reg #: 2596-RAA
Submission Type: New Registration
Resubmission? ☐ Yes ☒ No
Decision #: 445037; R310; NEW PRODUCT NON-FAST TRACK (INCLUDE:
Submitter Company: THE HARTZ MOUNTAIN CORP
Application Date: 04-Feb-2011
OPP Received Date: 08-Feb-2011 Date Sent to Risk Manager: 24-Feb-2011
Studies Included? ☐ Yes ☒ No Fast Track? ☐ Yes ☒ No
Form A Signed? ☐ Yes ☐ No ☒ None Date:
Form B Signed? ☐ Yes ☐ No ☒ None Date:
Reviewer: Akim Osolu, Bonaventure
Received DT: Editable Due DT:
Submission Due DT: 08-Sep-2011 Response DT: 08-Feb-2011
Priority Weight: Priority Points:
Comments: New Registration

DATA PACKAGE BEAN SHEET

Date: 14-Apr-2011

Page 1 of 1

Decision #: 445037

DP #: (388644)

PRIA

Parent DP #:

Submission #: 889997

*** Registration Information ***

Registration: 2596-RAA - HARTZ REFERENCE #131

Company: 2596 - THE HARTZ MOUNTAIN CORP.

Risk Manager: RM 10 - Richard Gebken - (703) 305-6701 Room# PY1 S-7237

Risk Manager Reviewer: Bonaventure Akinlosotu BAKINLOS

Sent Date: Calculated Due Date: 08-Sep-2011

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (R310) NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT CHEMIST

Ingredients: 129121, Fipronil(9.8%)

105402, S-Methoprene(11.8%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 14-Apr-2011

Due Back:

DP Ingredient: 105402, S-Methoprene

129121, Fipronil

DP Title: CAS

CSF Included: ☐ Yes ☒ No

Label Included: ☐ Yes ☒ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: RD / TRB

Last Possible Science Due Date: 09-Aug-2011

Team Name: TOX

Science Due Date:

Reviewer Name: Backus, Byron

Sub Data Package Due Date:

Contractor Name:

*** Studies Sent for Review ***

No Studies

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

For your review: An R310

Thnx, B.A (703-605-0653)

prev. rev
DP 388641

DATA PACKAGE BEAN SHEET

Date: 14-Apr-2011

Page 1 of 1

Decision #: 445037

DP #: (388641)

PRIA

Parent DP #:

Submission #: 889997

*** Registration Information ***

Registration: 2596-RAA - HARTZ REFERENCE #131

Company: 2596 - THE HARTZ MOUNTAIN CORP.

Risk Manager: RM 10 - Richard Gebken - (703) 305-6701 Room# PY1 S-7237

Risk Manager Reviewer: Bonaventure Akinlosotu BAKINLOS

Sent Date:

Calculated Due Date: 08-Sep-2011

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (R310) NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT CHEMIS1

Ingredients: 129121, Fipronil(9.6%)

105402, S-Methoprene(11.8%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 14-Apr-2011

Due Back:

DP Ingredient: 105402, S-Methoprene

129121, Fipronil

DP Title: tox/pl

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: RD / TRB

Last Possible Science Due Date: 09-Aug-2011

Team Name: TOX

Science Due Date:

Reviewer Name:

Sub Data Package Due Date:

Contractor Name:

*** Studies Sent for Review ***

No Studies

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

For your review: An R310

Thnx. B.A (703-605-0653)

R310
#28724

8/31

Hartz® Reference # 131

Alternate Brand Names

Hartz® UltraGuard Plus® Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)

Hartz® UltraGuard Pro® Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)

Hartz® UltraGuard Max™ Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)

Hartz® InControl Advanced® Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)

Hartz® InControl Max™ Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)

Revo™ Advanced™ Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)

Hartz® Revo Advanced™ Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)

Hartz® Pro Force™ Dual Action Topical Treatment for Cats (& Kittens)

Hartz® FieldForce™ Dual Action Topical Treatment for Cats (& Kittens)

Hartz® First Defense™ Dual Action Topical Treatment for Cats (& Kittens)

Hartz® Pro Force™ for Cats (& Kittens)

Hartz® FieldForce™ for Cats (& Kittens)

Hartz® First Defense™ for Cats (& Kittens)

Hartz® UltraGuard Plus® Flea (and) (&) Tick Topical Solution for Cats (& Kittens)

Hartz® UltraGuard Pro® Flea (and) (&) Tick Topical Solution for Cats (& Kittens)

Hartz® UltraGuard Max™ Flea (and) (&) Tick Topical Solution for Cats (& Kittens)

Hartz® InControl Advanced® Flea (and) (&) Tick Topical Solution for Cats (& Kittens)

Hartz® InControl Max™ Flea (and) (&) Tick Topical Solution for Cats (& Kittens)

Revo Advanced™ Flea (and) (&) Tick Topical Solution for Cats (& Kittens)

Hartz® Revo Advanced™ Flea (and) (&) Tick Topical Solution for Cats (& Kittens)

Hartz® Pro Force™ Dual Action Topical Solution for Cats (& Kittens)

Hartz® FieldForce™ Dual Action Topical Solution for Cats (& Kittens)

Hartz® First Defense™ Dual Action Topical Solution for Cats (& Kittens)

FieldForce™ Dual Action Topical Treatment for Cats (& Kittens)

First Defense™ Dual Action Topical Treatment for Cats (& Kittens)

FieldForce™ for Cats (& Kittens)

First Defense™ for Cats (& Kittens)

FieldForce™ Dual Action Topical Solution for Cats (& Kittens)

First Defense™ Dual Action Topical Solution for Cats (& Kittens)

ACTIVE INGREDIENTS:

Fipronil.....9.80%

(S)-Methoprene.....11.80%

OTHER INGREDIENTS78.40%

TOTAL100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for additional precautionary statements.

NET CONTENTS: Contains *(number)* tubes, each ___ fl. oz. (___ ml)

EPA Reg. No. 2596-RAA
EPA Est. No.

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.
Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS. CAUTION.

Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling.

HAZARDS TO DOMESTIC ANIMALS.

For external use only. Do not use on kittens under 8 weeks of age. Individual sensitivities, while rare, may occur after using any pesticide product. Pets may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian immediately. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged animals. Call 1-800-275-1414 for 24-hour assistance.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE: Do not use or store near heat or open flame.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents, you may call 1-800-275-1414.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Flush eyes with plenty of water. Call a doctor if irritation persists.

IF ON SKIN OR CLOTHING: Wash with plenty of soap and water. Get medical attention if irritation persists.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR PET READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.

To kill fleas, all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks [which may carry Lyme disease], chewing lice and mosquitoes, apply to cats and kittens [8 weeks or older] as follows:

[USE DIRECTIONS HERE]

(The application steps below may optionally be numbered or bulleted to clarify the order, depending on the final physical layout of the label)

[Option 1 capped tube]

Remove one applicator tube from the package and hold in an upright position (pointed away from your face). Pull off cap. Turn the cap around and place on top of tube. Simply press cap down to break the seal of the tube. Remove cap carefully. Position the tip of the tube on the cat's back between the shoulder blades. Use the tip of the tube to part the cat's hair so that the product will be applied at skin level. (Do not bathe your cat 48 hours prior to application.) Squeeze applicator, applying entire contents in a single spot on the animal's skin. Separate treated cat from other (dogs and cats) (pets) for 24 hours after treatment has been applied. Repeat every month.

[Option 2 applicator tube]

Remove one applicator tube from the package and hold in an upright position pointed away from your face. Twist dispensing tip clockwise about ½ turn while pushing down to break the tube's seal. Do not remove the dispensing tip. Position the dispensing tip on the cat's back between the shoulder blades. Use the dispensing tip of the tube to part the cat's hair so that the product will be applied at skin level. (Do not bathe your cat 48 hours prior to application.) Squeeze applicator, applying entire contents in a single spot on the animal's skin. Separate treated cat from other (dogs and cats) (pets) for 24 hours after treatment has been applied. Repeat every month.

PRODUCT NAME contains Fipronil and the insect growth regulatory (IGR) (S)-Methoprene. PRODUCT NAME effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, chewing lice and mosquitoes.

PRODUCT NAME can also be used for the treatment and control of mosquitoes, and flea, tick and chewing lice infestations on breeding, pregnant and lactating queens.

FREQUENCY OF APPLICATION

When used monthly, PRODUCT NAME completely breaks the flea life cycle and controls tick and chewing lice infestations. Research demonstrates that PRODUCT NAME kills adult fleas, flea eggs, and flea larvae for up to six weeks. PRODUCT NAME also prevents development of all flea stages for up to six weeks. PRODUCT NAME kills ticks for a least one month. A once monthly application is recommended where tick control is needed. Although PRODUCT NAME can control fleas for up to six weeks, if there is a high risk of reinfestation or if the pet has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

With a monthly application of PRODUCT NAME kills mosquitoes within 24 hours for up to 14 days and within 48 hours for up to 28 days.

PRODUCT NAME remains effective even after bathing, water immersion, or exposure to sunlight. Avoid contact with treated area until dry. Do not reapply PRODUCT NAME for 30 days.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

STORAGE. Store unused product in original container, out of reach of children and animals.

PESTICIDE DISPOSAL. If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

CONTAINER DISPOSAL. If empty: Do not reuse this container. Place in trash or offer for recycling if available.

For more information call our (flea and tick) experts at 1-800-275-1414 (weekdays, 9 am – 5 pm E.S.T.)

INDIVIDUAL TUBE TEXT

Product Name

Active Ingredients:

Fipronil 9.8%, (S)-Methoprene 11.8%

Keep Out of Reach of Children

Caution

Read accompanying label before use

EPA Reg. No. 2596-RAA

EPA Est. No.

Product Name can also be used for the treatment and control of mosquitoes, and flea, tick and chewing lice infestations on breeding, pregnant and lactating queens.

Product Name contains Fipronil and the insect growth regulator (IGR) (S)-Methoprene. Product Name effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, chewing lice and mosquitoes.

Stops and prevents infestations

Kills adult fleas, flea eggs, and flea larvae

Prevents all flea stages (eggs, larvae, pupae) from developing

Kills fleas which may cause flea allergy dermatitis

Kills all stages of Deer Ticks (which may carry Lyme disease), Brown Dog Ticks, American Dog Ticks, and Lone Star Ticks

Kills mosquitoes

Prevents and controls reinfestations

Rapidly eliminates infestations with chewing lice

Can also be used on breeding, pregnant and lactating queens

Fast-acting

Long-lasting

Waterproof

Convenient to use

[Adult Fleas]

Kills Fleas (that may transmit tapeworms) (for) (28 days) (30 days) (1 month) (4 weeks) (on cats)

Kills (Adult) Fleas (for up to 3 months)

Kills fleas that may cause (flea allergy dermatitis) (and) (flea bite anemia) (for) (28 days) (30 days) (1 month) (4 weeks) (3 months) (on cats)

Kills newly emerged adult Fleas before they lay eggs

If there is a high risk for flea reinfestation, a once a month application may be needed

Stops existing infestations
Prevents establishment of new infestations

[Flea Eggs]

Kills Flea Eggs (and Flea Larvae) (for) (28 days) (30 days) (1 month) (4 weeks)
Prevents Flea Eggs from hatching

[Ticks]

Kills Ticks (for) (28 days) (30 days) (1 month) (4 weeks)
Kills (all stages of) Brown Dog Ticks, American Dog Ticks, Lone Star Ticks and Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)
Kills (all stages of) Deer Ticks (that may carry Lyme disease) (for) (28 days) (30 days) (1 month) (4 weeks) (on cats)
Kills all biting stages of ticks
Kills adult (brown dog) (deer) ticks, nymphs and larvae
Kills Ticks including those that may transmit Lyme disease

[Lice & Mange]

Rapidly eliminates chewing lice infestations
Aids in Control of sarcoptic mange infestations

[Multiple]

Kills Fleas, Ticks, Flea eggs, Chewing Lice, (Flea larvae)
Kills Fleas, Ticks, Flea eggs, (Flea larvae) (through contact) (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea Eggs, (Flea larvae), (Chewing lice) (through contact) (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea eggs, (Flea larvae) (after contact) (for) (28 days) (30 days) (1 month) (4 weeks)
Prevents development of all flea stages for up to 3 months.
Kills adult Fleas, Flea Eggs and Larvae (for up to three months)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, (Flea larvae) (after contact) (for) (28 days) (30 days) (1 month) (4 weeks)
Controls Flea and Tick infestations (on cats) (for) (28 days) (30 days) (1 month) (4 weeks)
Provides fast, effective and convenient treatment and control of fleas, ticks, chewing lice and mosquitoes (for cats and kittens)

Helps prevent re-infestation of fleas and ticks (for) (28 days) (30 days) (1 month) (4 weeks)
Helps prevent flea and tick re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)
Kills flea eggs and flea larvae to help prevent future re-infestations
Kills all stages of the flea life cycle
Breaks the flea life cycle
Prevents all flea stages (eggs, larvae, pupae) from developing

[Mosquitoes]

Kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.
Kills Mosquitoes that may transmit West Nile virus (for) (28 days)(1 month) (4 weeks)(on cats)
Kills Mosquitoes that may transmit heartworm (for) (28 days)(1 month) (4 weeks)(on cats)

Controls flea and tick infestations

Once-a month Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Monthly Flea and Tick (Prevention) (Treatment) (Control) (Solution)

(28 day) (30 day) (1 month) (4 week) Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Prevents flea eggs from developing into biting adults (for) (up to) (30 days) (1 month) (4 weeks)

Gentle protection for cats (and kittens)

Quick drying (formula)

Dries quickly

Stays on and doesn't rub off

Spreads with cat's natural skin oils

Kills fleas for 30 days (1 month) (4 weeks)

Stops and prevents infestations

Prevents re-infestation

Prevents and controls re-infestation(s)

Rapidly eliminates fleas

Fast acting

Long lasting

Effective and convenient topical treatment

Kills fleas (and ticks) through (after) contact

(With) patented applicator

(With) patent pending applicator

Waterproof

Easy spot on topical applicator

Do not reapply product for 30 days

Remains effective even after bathing, water immersion, or exposure to sunlight

(Product Name) remains effective even after bathing, water immersion, or exposure to sunlight.

Avoid contact with treated area until dry.

Can also be used on breeding, pregnant and lactating queens

Convenient to use

Contains Fipronil and the insect growth regulator (IGR) (S)-Methoprene. (product name) effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks and chewing lice.

New (Formula) *(claim to be removed after 6 months)*

Contains Fipronil and (S)-Methoprene (, the active ingredients used in Frontline Plus®).

(Brand name) is not manufactured by or distributed by Merial. Frontline Plus® is a registered trademark of Merial.

Compare to Frontline Plus®

For cats and kittens 8 weeks of age or older

Specially formulated for cats and kittens

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

1st dose, 2nd dose, 3rd dose (Xth dose)

First month, second month, third month (Xth month)

X-pack

X-tubes

Value pack

X month supply

X monthly treatment(s)

Fragrance-free

Unscented

Fresh (scent) (fragrance)

Powder (scent) (fragrance)

Pleasant (scent) (fragrance)

Spring Fresh Scent

Convenient (easy to use) applicator

X Pro-cision Flo® Applicator(s)

With Pro-cision Flo® Applicator

Featuring Pro-cision Flo® Applicator (for easy application)

Direct to your cat's skin

Easy (simple) to use (handle) (apply)

(Featuring the) (with) EZC™ tube

(Featuring the) (with) EZ2C™ tube

(Featuring the) (with) EZView™ tube

(Featuring the) (with) EZView™ tube

(Featuring the) (with) Clearview™ tube

(Featuring the) (with) Clearview™ tube

(Clearview™) (EZC™) (EZ2C™) (EZView™) tube (visually) ensures all product has been dispensed

(Clearview™) (EZC™) (EZ2C™) (EZView™) tubes give you the assurance all the product has been applied

After application, the treated area may appear wet (or) (oily) for up to 24 hours

You may bathe your cat 48 hours after application

To help remind you when you last applied treatment, simply write in the date when each dose is applied:

First Dose _____

Second Dose _____

Third Dose _____

Xth Dose _____

Hartz[®] and other trademarks are trademarks of The Hartz Mountain Corporation



THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094-3688 • 201/271-4800

June 13, 2011

Document Processing Desk
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: Mr. Richard Gebken (PM # 10)

**Addendum to Existing Protocol for Child Resistant Packaging
for Products containing Fipronil**

***Hartz Reference #128, EPA File Symbol 2596-RAG
Hartz Reference #129, EPA File Symbol 2596-RAU
Hartz Reference #130, EPA File Symbol 2596-RAL
Hartz Reference #131, EPA File Symbol 2596-RAA***

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688 is submitting an addendum to our existing protocol to add an additional product tube with laminate construction for testing of packaging to determine whether packages of end-use products containing the active ingredient, Fipronil, are child resistant.

The additional product tube with laminate construction has been included in the protocol for child resistant packaging in the Package Description Section 2.2.2.

The Hartz Mountain Corporation is submitting the following:

- Hartz Test #2278, Hartz UltraGuard Flea and Tick Topical Treatment, Child-resistant Package Test Protocol, Prepared by National Child Resistant Testing, Inc., Lincoln, NE – 3 copies **dated June 7, 2011.**

If you have any questions or need additional information, please feel free to contact me at (201) 271-4800, ext. 7202 or mailto:rosenwasser@hartz.com.

Sincerely,

Robert Rosenwasser
Director, Regulatory Affairs

Explore Registrations

Reg Number: 2596-RAA Reg Type: Product Registration - Section 3 Status: Under Review (09-Feb-2011)
 Name: HARTZ REFERENCE #131 <View Registration Details>

(New Receipts)

S	Submission Type	OPP Rec'd Date	Resubmission	Description
884962	Pending Product Amendment	02-May-2011	<input type="radio"/> Yes <input checked="" type="radio"/> No	CSF amendment

...Decisions...

- Data Requirements
- D: Pending; 445037; 2596-RAA; R310; NEW PRO
- 75-Day Letters
- S: 901779 6/14/2011; New Registration; 2596
- S: 905591 5/2/2011; New Registration; 2596
- S: 889997 2/8/2011; New Registration; 2596

S: 895591 Reg #: 2596-RAA
 Submission Type: New Registration
 Resubmission?: ☒ Yes ☐ No E-Sub #:
 Decision #: 445037; R310; NEW PRODUCT NON-FAST TRACK (INCLUDES
 Submitter Company: THE HARTZ MOUNTAIN CORPORATION
 Application Date: 28-Apr-2011
 OPP Received Date: 02-May-2011 Date Sent to Risk manager: 03-May-2011
 Studies Included?: ☐ Yes ☒ No Fast Track?: ☐ Yes ☒ No
 Form A Signed?: ☐ Yes ☐ No ☒ None Date:
 Form B Signed?: ☐ Yes ☐ No ☒ None Date:
 Reviewer: Akinlosotu, Bonaventure
 Received DT: Editable Due DT:
 Submission Due DT: 08-Mar-2012 Response: 02-May-2011
 Priority Weight: Priority Points:
 Comments: Resubmission to existing PRIA

Executive Information System (EIS) - 1.1.1			
System Overview		System Details	
System Name: [REDACTED]		System ID: [REDACTED]	
System Version: [REDACTED]		System Status: [REDACTED]	
System Description: [REDACTED]		System Configuration: [REDACTED]	
System Architecture: [REDACTED]		System Components: [REDACTED]	
System Security: [REDACTED]		System Performance: [REDACTED]	
System Maintenance: [REDACTED]		System Support: [REDACTED]	
System Documentation: [REDACTED]		System Training: [REDACTED]	
System Testing: [REDACTED]		System Deployment: [REDACTED]	
System Monitoring: [REDACTED]		System Reporting: [REDACTED]	
System Audit: [REDACTED]		System Review: [REDACTED]	
System Change: [REDACTED]		System Upgrade: [REDACTED]	
System Retirement: [REDACTED]		System Archiving: [REDACTED]	
System Decommission: [REDACTED]		System Disposal: [REDACTED]	
System Reuse: [REDACTED]		System Recycling: [REDACTED]	
System Security: [REDACTED]		System Performance: [REDACTED]	
System Maintenance: [REDACTED]		System Support: [REDACTED]	
System Documentation: [REDACTED]		System Training: [REDACTED]	
System Testing: [REDACTED]		System Deployment: [REDACTED]	
System Monitoring: [REDACTED]		System Reporting: [REDACTED]	
System Audit: [REDACTED]		System Review: [REDACTED]	
System Change: [REDACTED]		System Upgrade: [REDACTED]	
System Retirement: [REDACTED]		System Archiving: [REDACTED]	
System Decommission: [REDACTED]		System Disposal: [REDACTED]	
System Reuse: [REDACTED]		System Recycling: [REDACTED]	

DATA PACKAGE BEAN SHEET

Date: 14-Apr-2011

Page 1 of 1

Decision #: 445037

DP #: (388643)

PRIA

Parent DP #:

Submission #: 889997

*** Registration Information ***

Registration: 2596-RAA - HARTZ REFERENCE #131

Company: 2596 - THE HARTZ MOUNTAIN CORP.

Risk Manager: RM 10 - Richard Gebken - (703) 305-6701 Room# PY1 S-7237

Risk Manager Reviewer: Bonaventure Akinlosotu BAKINLOS

Sent Date:

Calculated Due Date: 08-Sep-2011

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (R310) NEW PRODUCT, NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT CHEMIST

Ingredients: 129121, Fipronil(9.8%)

105402, S-Methoprene(11.8%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 14-Apr-2011

Due Back:

DP Ingredient: 105402, S-Methoprene

129121, Fipronil

DP Title: Efficacy

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: RD / IB

Last Possible Science Due Date: 09-Aug-2011

Team Name: Efficacy (IB)

Science Due Date:

Reviewer Name: C. Myers

Sub Data Package Due Date:

Contractor Name:

*** Studies Sent for Review ***

No Studies

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

For your review: An R310

Thnx, B.A (703-605-0653)



483792-00

THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094 201/271-4800
REGULATORY AFFAIRS

February 7, 2011

Document Processing Desk (APPL)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: **Mr. Richard Gebken (PM # 10)**
RE: HARTZ REF #128, EPA Reg. No. 2596-RAG
HARTZ REF #129, EPA Reg. No. 2596-RAU
HARTZ REF #130, EPA Reg. No. 2596-RAL
HARTZ REF #131, EPA Reg. No. 2596-RAA

PRIA CODE = R310

Dear Mr. Gebken:

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688 is filing this application to register 4 new products that are based on the Cite-All Method of Support from Merial.

A complete Transmittal Document is attached which states all the documents that are being submitted in support of this registration.

A check for \$19,228 is also enclosed to cover the application fees for the 4 new products and is submitted under PRIA Code R310.

If you have any questions or need any additional information, please feel free to call me at (201) 271-4800, ext. 7202 or <mailto:rosenwasser@hartz.com>.

Sincerely yours,

Robert Rosenwasser
Director, Regulatory Affairs

TRANSMITTAL DOCUMENT

1. NAME AND ADDRESS OF SUBMITTER

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094

2. REGULATORY ACTION IN SUPPORT OF WHICH THESE PACKAGES ARE SUBMITTED

Applications for Registration of 4 new products containing:

Fipronil; Hartz Reference #128, EPA File Symbol 2596-RAG

Fipronil; Hartz Reference #129, EPA File Symbol 2596-RAU

Fipronil and (S)-Methoprene; Hartz Reference #130, EPA File Symbol 2596-RAL

Fipronil and (S)-Methoprene; Hartz Reference #131, EPA File Symbol 2596-RAA

3. TRANSMITTAL DATE February 7, 2011

4. LIST OF SUBMITTED DOCUMENTS

For Reference #128, EPA File Symbol 2596-RAG

VOLUME 1	Product Chemistry Self-Certification	(3 copies)
VOLUME 2	Product Chemistry Product Identity and Composition, Analysis, Certification of Ingredients Manufacturing Process Discussion of Impurities Confidential Statement of Formula	(3 copies)
VOLUME 3	Product Chemistry: Enforcement Analytical Method Method is also applicable to Hartz Reference #129, EPA File Symbol 2596-RAU	(3 copies)

For Reference #129, EPA File Symbol 2596-RAU

VOLUME 1	Product Chemistry Self-Certification,	(3 copies)
VOLUME 2	Product Chemistry Product Identity and Composition, Analysis, Certification of Ingredients Manufacturing Process Discussion of Impurities Confidential Statement of Formula	(3 copies)
VOLUME 3	Product Chemistry: Enforcement Analytical Method	(See above)

For Reference #130, EPA File Symbol 2596-RAL

VOLUME 1	Product Chemistry Self-Certification,	(3 copies)
VOLUME 2	Product Chemistry Product Identity and Composition, Analysis, Certification of Ingredients Manufacturing Process Discussion of Impurities Confidential Statement of Formula	(3 copies)
VOLUME 3	Product Chemistry: Enforcement Analytical Method Method is also applicable to Hartz Reference #131, EPA File Symbol 2596-RAA	(3 copies)

For Reference #131, EPA File Symbol 2596-RAA

1379201 VOLUME 1	Product Chemistry Self-Certification	(3 copies)
1379202 VOLUME 2	Product Chemistry Product Identity and Composition, Analysis, Certification of Ingredients Manufacturing Process Discussion of Impurities Confidential Statement of Formula	(3 copies)
VOLUME 3	Product Chemistry: Enforcement Analytical Method	(See above)

For each application, the following documents are submitted:

1. Completed Application Form (8570-1)
2. Data Matrix
3. Certification with Respect to Citation of Data (8570-34)
4. Data Matrix listing company that is utilized in cite-all method.
5. Completed Confidential Statement of Formulas (One loose copy and one copy in Vol. 2 Product Chemistry)
6. Product labels, 6 copies each.
7. Check in the amount of \$19,228 for 4 applications, PRIA Code R310.

5. COMPANY OFFICIAL Robert Rosenwasser, Director, Regulatory Affairs

6. SIGNATURE

7. PHONE 201-271-4800, ext. 7202

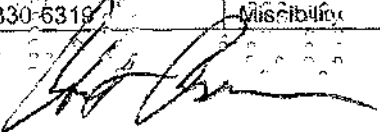


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date February 4, 2011			EPA Reg. No. 2596-RAA		Page 1 of 2
Applicant's/Registrant's Name & Address: Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094			Product Hartz Reference #131		
Ingredient Fipronil, (S)-methoprene					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830-1550	Product identification and composition	submitted	Hartz	Own	
830-1600	Beginning materials	submitted	Hartz	Own	
830-1650	Description of formulation process	submitted	Hartz	Own	
830-1670	Formation of impurities	submitted	Hartz	Own	
830-1750	Certified limits	submitted	Hartz	Own	
830-1800	Enforcement analytical method	submitted	Hartz	Own	
830-6302	Color	submitted	Hartz	Own	Self-certification
830-6303	Physical state	submitted	Hartz	Own	Self-certification
830-6304	Odor	submitted	Hartz	Own	Self-certification
830-6314	Oxidation/Reduction	Waiver	Hartz	Own	Self-certification
830-6315	Flammability	submitted	Hartz	Own	Self-certification
830-6316	Explosibility	Waiver	End use product is not potentially explosive.		
830-6317	Storage stability	To be submitted	Hartz	Own	In progress
830-6318	Miscibility	Waiver	End use product is not to be diluted with petroleum solvents.		
Signature 			Name and Title Robert Rosenwasser Director, Regulatory Affairs		Date February 4, 2011

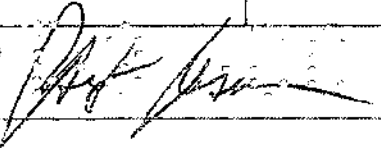


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
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DATA MATRIX

Date February 4, 2011			EPA Reg. No. 2596-RAA		Page 2 of 2
Applicant's/Registrant's Name & Address: Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094			Product Hartz Reference #131		
Ingredient Fipronil, (S)-methoprene					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830-6320	Corrosion characteristics	To be submitted	Hartz	Own	In progress
830-6321	Dielectric breakdown voltage	Waiver	End use product is not to be used around electrical equipment.		
830-7000	pH	Waiver	End use product is not to be dispersed with water.		
830-7100	Viscosity	submitted	Hartz	Own	Self-certification
830-7300	Density	submitted	Hartz	Own	Self-certification
Signature 			Name and Title Robert Rosenwasser Director, Regulatory Affairs		Date February 4, 2011



401 M Street, S.W.

WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director, OPPE Information Management Division (2137) U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date February 4, 2011

EPA Reg. No. 2596-RAA

Page 1 of 1

Applicant's/Registrant's Name & Address: Hartz Mountain Corporation, 400 Plaza Dr.,
Secaucus, NJ 07094

Product
Hartz Reference #131

Ingredient Flpronil, (S)-methoprene

54

Hartz® Reference # 131

Alternate Brand Names

Hartz® UltraGuard Plus® Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)
Hartz® UltraGuard Pro® Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)
Hartz® UltraGuard Max™ Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)

Hartz® InControl Advanced® Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)
Hartz® InControl Max™ Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)

Revo™ Advanced™ Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)

Hartz® Revo Advanced™ Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)

Hartz® Pro Force™ Dual Action Topical Treatment for Cats (& Kittens)
Hartz® FieldForce™ Dual Action Topical Treatment for Cats (& Kittens)
Hartz® First Defense™ Dual Action Topical Treatment for Cats (& Kittens)

Hartz® Pro Force™ for Cats (& Kittens)
Hartz® FieldForce™ for Cats (& Kittens)
Hartz® First Defense™ for Cats (& Kittens)
Hartz® UltraGuard Plus® Flea (and) (&) Tick Topical Solution for Cats (& Kittens)
Hartz® UltraGuard Pro® Flea (and) (&) Tick Topical Solution for Cats (& Kittens)
Hartz® UltraGuard Max™ Flea (and) (&) Tick Topical Solution for Cats (& Kittens)
Hartz® InControl Advanced® Flea (and) (&) Tick Topical Solution for Cats (& Kittens)
Hartz® InControl Max™ Flea (and) (&) Tick Topical Solution for Cats (& Kittens)
Revo Advanced™ Flea (and) (&) Tick Topical Solution for Cats (& Kittens)
Hartz® Revo Advanced™ Flea (and) (&) Tick Topical Solution for Cats (& Kittens)
Hartz® Pro Force™ Dual Action Topical Solution for Cats (& Kittens)
Hartz® FieldForce™ Dual Action Topical Solution for Cats (& Kittens)
Hartz® First Defense™ Dual Action Topical Solution for Cats (& Kittens)
FieldForce™ Dual Action Topical Treatment for Cats (& Kittens)
First Defense™ Dual Action Topical Treatment for Cats (& Kittens)
FieldForce™ for Cats (& Kittens)
First Defense™ for Cats (& Kittens)
FieldForce™ Dual Action Topical Solution for Cats (& Kittens)
First Defense™ Dual Action Topical Solution for Cats (& Kittens)

ACTIVE INGREDIENTS:

Fipronil.....	9.80%
(S)-Methoprene.....	11.80%
OTHER INGREDIENTS	78.40%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for additional precautionary statements.

NET CONTENTS: Contains (*number*) tubes, each ___ fl. oz. (___ ml)

EPA Reg. No. 2596-RAA
EPA Est. No.

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.
Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION.

Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling.

HAZARDS TO DOMESTIC ANIMALS.

For external use only. Do not use on kittens under 8 weeks of age. Individual sensitivities, while rare, may occur after using any pesticide product. Pets may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian immediately. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged animals. Call 1-800-275-1414 for 24-hour assistance.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE: Do not use or store near heat or open flame.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents, you may call 1-800-275-1414.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Flush eyes with plenty of water. Call a doctor if irritation persists.

IF ON SKIN OR CLOTHING: Wash with plenty of soap and water. Get medical attention if irritation persists.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR PET READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.

To kill fleas, all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks [which may carry Lyme disease], chewing lice and mosquitoes, apply to cats and kittens [8 weeks or older] as follows:

[USE DIRECTIONS HERE]

(The application steps below may optionally be numbered or bulleted to clarify the order, depending on the final physical layout of the label)

[Option 1 capped tube]

Remove one applicator tube from the package and hold in an upright position (pointed away from your face). Pull off cap. Turn the cap around and place on top of tube. Simply press cap down to break the seal of the tube. Remove cap carefully. Position the tip of the tube on the cat's back between the shoulder blades. Use the tip of the tube to part the cat's hair so that the product will be applied at skin level. (Do not bathe your cat 48 hours prior to application.) Squeeze applicator, applying entire contents in a single spot on the animal's skin. Separate treated cat from other (dogs and cats) (pets) for 24 hours after treatment has been applied. Repeat every month.

[Option 2 applicator tube]

Remove one applicator tube from the package and hold in an upright position pointed away from your face. Twist dispensing tip clockwise about ½ turn while pushing down to break the tube's seal. Do not remove the dispensing tip. Position the dispensing tip on the cat's back between the shoulder blades. Use the dispensing tip of the tube to part the cat's hair so that the product will be applied at skin level. (Do not bathe your cat 48 hours prior to application.) Squeeze applicator, applying entire contents in a single spot on the animal's skin. Separate treated cat from other (dogs and cats) (pets) for 24 hours after treatment has been applied. Repeat every month.

PRODUCT NAME contains Fipronil and the insect growth regulatory (IGR) (S)-Methoprene. PRODUCT NAME effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, chewing lice and mosquitoes.

PRODUCT NAME can also be used for the treatment and control of mosquitoes, and flea, tick and chewing lice infestations on breeding, pregnant and lactating queens.

FREQUENCY OF APPLICATION

When used monthly, PRODUCT NAME completely breaks the flea life cycle and controls tick and chewing lice infestations. Research demonstrates that PRODUCT NAME kills adult fleas, flea eggs, and flea larvae for up to six weeks. PRODUCT NAME also prevents development of all flea stages for up to six weeks. PRODUCT NAME kills ticks for a least one month. A once monthly application is recommended where tick control is needed. Although PRODUCT NAME can control fleas for up to six weeks, if there is a high risk of reinfestation or if the pet has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

With a monthly application of PRODUCT NAME kills mosquitoes within 24 hours for up to 14 days and within 48 hours for up to 28 days.

PRODUCT NAME remains effective even after bathing, water immersion, or exposure to sunlight. Avoid contact with treated area until dry. Do not reapply PRODUCT NAME for 30 days.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

STORAGE. Store unused product in original container, out of reach of children and animals.

PESTICIDE DISPOSAL. If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

CONTAINER DISPOSAL. If empty: Do not reuse this container. Place in trash or offer for recycling if available.

For more information call our (flea and tick) experts at 1-800-275-1414 (weekdays, 9 am – 5 pm E.S.T.)

INDIVIDUAL TUBE TEXT

Product Name

Active Ingredients:

Fipronil 9.8%, (S)-Methoprene 11.8%

Keep Out of Reach of Children

Caution

Read accompanying label before use

EPA Reg. No. 2596-RAA

EPA Est. No.

Product Name can also be used for the treatment and control of mosquitoes, and flea, tick and chewing lice infestations on breeding, pregnant and lactating queens.

Product Name contains Fipronil and the insect growth regulator (IGR) (S)-Methoprene. Product Name effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, chewing lice and mosquitoes.

Stops and prevents infestations

Kills adult fleas, flea eggs, and flea larvae

Prevents all flea stages (eggs, larvae, pupae) from developing

Kills fleas which may cause flea allergy dermatitis

Kills all stages of Deer Ticks (which may carry Lyme disease), Brown Dog Ticks, American Dog Ticks, and Lone Star Ticks

Kills mosquitoes

Prevents and controls reinfestations

Rapidly eliminates infestations with chewing lice

Can also be used on breeding, pregnant and lactating queens

Fast-acting

Long-lasting

Waterproof

Convenient to use

[Adult Fleas]

Kills Fleas (that may transmit tapeworms) (for) (28 days) (30 days) (1 month) (4 weeks) (on cats)

Kills (Adult) Fleas ~~(for up to 3 months)~~

Kills fleas that may cause (flea allergy dermatitis) (and) (flea bite anemia) (for) (28 days) (30 days) (1 month) (4 weeks) ~~(3 months)~~ (on cats)

Kills newly emerged adult Fleas before they lay eggs

If there is a high risk for flea reinfestation, a once a month application may be needed

Stops existing infestations
Prevents establishment of new infestations

[Flea Eggs]

Kills Flea Eggs (and Flea Larvae) (for) (28 days) (30 days) (1 month) (4 weeks)
Prevents Flea Eggs from hatching

[Ticks]

Kills Ticks (for) (28 days) (30 days) (1 month) (4 weeks)
Kills (all stages of) Brown Dog Ticks, American Dog Ticks, Lone Star Ticks and Deer Ticks
(for) (28 days) (30 days) (1 month) (4 weeks)
Kills (all stages of) Deer Ticks (that may carry Lyme disease) (for) (28 days) (30 days) (1
month) (4 weeks) (on cats)
Kills all biting stages of ticks
Kills adult (brown dog) (deer) ticks, nymphs and larvae
Kills Ticks including those that may transmit Lyme disease

[Lice & Mange]

Rapidly eliminates chewing lice infestations
Aids in Control of sarcoptic mange infestations

[Multiple]

Kills Fleas, Ticks, Flea eggs, Chewing Lice, (Flea larvae)
Kills Fleas, Ticks, Flea eggs, (Flea larvae) (through contact) (for) (28 days) (30 days) (1 month)
(4 weeks)
Kills Fleas, Ticks, Flea Eggs, (Flea larvae), (Chewing lice) (through contact) (for) (28 days) (30
days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea eggs, (Flea larvae) (after contact) (for) (28 days) (30 days) (1 month) (4
weeks)
Prevents development of all flea stages for up to 3 months.
Kills adult Fleas, Flea Eggs and Larvae (for up to three months)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, (Flea larvae) (after contact) (for) (28 days)
(30 days) (1 month) (4 weeks)
Controls Flea and Tick infestations (on cats) (for) (28 days) (30 days) (1 month) (4 weeks)
Provides fast, effective and convenient treatment and control of fleas, ticks, chewing lice and
mosquitoes (for cats and kittens)

Helps prevent re-infestation of fleas and ticks (for) (28 days) (30 days) (1 month) (4 weeks)
Helps prevent flea and tick re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)
Kills flea eggs and flea larvae to help prevent future re-infestations
Kills all stages of the flea life cycle
Breaks the flea life cycle
Prevents all flea stages (eggs, larvae, pupae) from developing

[Mosquitoes]

Kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.

Kills Mosquitoes that may transmit West Nile virus (for) (28 days)(1 month) (4 weeks)(on cats)

Kills Mosquitoes that may transmit heartworm (for) (28 days)(1 month) (4 weeks)(on cats)

Controls flea and tick infestations

Once-a month Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Monthly Flea and Tick (Prevention) (Treatment) (Control) (Solution)

(28 day) (30 day) (1 month) (4 week) Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Prevents flea eggs from developing into biting adults (for) (up to) (30 days) (1 month) (4 weeks)

Gentle protection for cats (and kittens)

Quick drying (formula)

Dries quickly

Stays on and doesn't rub off

Spreads with cat's natural skin oils

Kills fleas for 30 days (1 month) (4 weeks)

Stops and prevents infestations

Prevents re-infestation

Prevents and controls re-infestation(s)

Rapidly eliminates fleas

Fast acting

Long lasting

Effective and convenient topical treatment

Kills fleas (and ticks) through (after) contact

(With) patented applicator

(With) patent pending applicator

Waterproof

Easy spot on topical applicator

Do not reapply product for 30 days

Remains effective even after bathing, water immersion, or exposure to sunlight

(Product Name) remains effective even after bathing, water immersion, or exposure to sunlight.

Avoid contact with treated area until dry.

Can also be used on breeding, pregnant and lactating queens

Convenient to use

Contains Fipronil and the insect growth regulator (IGR) (S)-Methoprene. (product name)

effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks and chewing lice.

New (Formula) (*claim to be removed after 6 months*)

Contains Fipronil and (S)-Methoprene (, the active ingredients used in Frontline Plus®).

(Brand name) is not manufactured by or distributed by Merial. Frontline Plus® is a registered trademark of Merial.

Compare to Frontline Plus®

For cats and kittens 8 weeks of age or older
Specially formulated for cats and kittens

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

1st dose, 2nd dose, 3rd dose (Xth dose)

First month, second month, third month (Xth month)

X-pack

X-tubes

Value pack

X month supply

X monthly treatment(s)

Fragrance-free

Unscented

Fresh (scent) (fragrance)

Powder (scent) (fragrance)

Pleasant (scent) (fragrance)

Spring Fresh Scent

Convenient (easy to use) applicator

X Pro-cision Flo® Applicator(s)

With Pro-cision Flo® Applicator

Featuring Pro-cision Flo® Applicator (for easy application)

Direct to your cat's skin

Easy (simple) to use (handle) (apply)

(Featuring the) (with) EZC™ tube

(Featuring the) (with) EZ2C™ tube

(Featuring the) (with) EZView™ tube

(Featuring the) (with) EZView™ tube

(Featuring the) (with) Clearview™ tube

(Featuring the) (with) Clearview™ tube

(Clearview™) (EZC™) (EZ2C™) (EZView™) tube (visually) ensures all product has been dispensed

(Clearview™) (EZC™) (EZ2C™) (EZView™) tubes give you the assurance all the product has been applied

After application, the treated area may appear wet (or) (oily) for up to 24 hours

You may bathe your cat 48 hours after application

To help remind you when you last applied treatment, simply write in the date when each dose is applied:

First Dose _____

Second Dose _____

Third Dose _____
Xth Dose _____

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation

Hartz® Reference # 131

Alternate Brand Names

Hartz® UltraGuard Plus® Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)
Hartz® UltraGuard Pro® Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)
Hartz® UltraGuard Max™ Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)

Hartz® InControl Advanced® Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)
Hartz® InControl Max™ Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)

Revo™ Advanced™ Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)

Hartz® Revo Advanced™ Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)

Hartz® Pro Force™ Dual Action Topical Treatment for Cats (& Kittens)
Hartz® FieldForce™ Dual Action Topical Treatment for Cats (& Kittens)
Hartz® First Defense™ Dual Action Topical Treatment for Cats (& Kittens)

Hartz® Pro Force™ for Cats (& Kittens)
Hartz® FieldForce™ for Cats (& Kittens)
Hartz® First Defense™ for Cats (& Kittens)
Hartz® UltraGuard Plus® Flea (and) (&) Tick Topical Solution for Cats (& Kittens)
Hartz® UltraGuard Pro® Flea (and) (&) Tick Topical Solution for Cats (& Kittens)
Hartz® UltraGuard Max™ Flea (and) (&) Tick Topical Solution for Cats (& Kittens)
Hartz® InControl Advanced® Flea (and) (&) Tick Topical Solution for Cats (& Kittens)
Hartz® InControl Max™ Flea (and) (&) Tick Topical Solution for Cats (& Kittens)
Revo Advanced™ Flea (and) (&) Tick Topical Solution for Cats (& Kittens)
Hartz® Revo Advanced™ Flea (and) (&) Tick Topical Solution for Cats (& Kittens)
Hartz® Pro Force™ Dual Action Topical Solution for Cats (& Kittens)
Hartz® FieldForce™ Dual Action Topical Solution for Cats (& Kittens)
Hartz® First Defense™ Dual Action Topical Solution for Cats (& Kittens)
FieldForce™ Dual Action Topical Treatment for Cats (& Kittens)
First Defense™ Dual Action Topical Treatment for Cats (& Kittens)
FieldForce™ for Cats (& Kittens)
First Defense™ for Cats (& Kittens)
FieldForce™ Dual Action Topical Solution for Cats (& Kittens)
First Defense™ Dual Action Topical Solution for Cats (& Kittens)

ACTIVE INGREDIENTS:

Fipronil.....	9.80%
(S)-Methoprene.....	11.80%
OTHER INGREDIENTS	78.40%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for additional precautionary statements.

NET CONTENTS: Contains (*number*) tubes, each __ fl. oz. (__ ml)

EPA Reg. No. 2596-RAA
EPA Est. No.

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.
Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION.

Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling.

HAZARDS TO DOMESTIC ANIMALS.

For external use only. Do not use on kittens under 8 weeks of age. Individual sensitivities, while rare, may occur after using any pesticide product. Pets may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian immediately. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged animals. Call 1-800-275-1414 for 24-hour assistance.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE: Do not use or store near heat or open flame.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents, you may call 1-800-275-1414.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Flush eyes with plenty of water. Call a doctor if irritation persists.

IF ON SKIN OR CLOTHING: Wash with plenty of soap and water. Get medical attention if irritation persists.

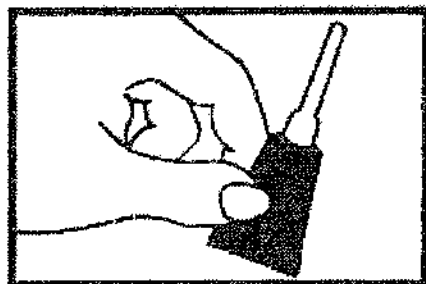
DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR PET READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.

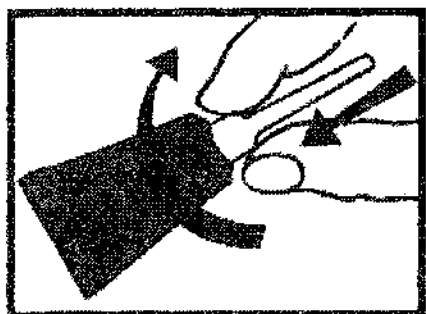
To kill fleas, all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks [which may carry Lyme disease], chewing lice and mosquitoes, apply to cats and kittens [8 weeks or older] as follows:

[USE DIRECTIONS HERE]

(The application steps below may optionally be numbered or bulleted to clarify the order, depending on the final physical layout of the label)



1 Remove one applicator tube from the package and hold in an upright position pointed away from your face.



2 Twist dispensing tip clockwise about ½ turn while pushing down to break the tube's seal. Do not remove the dispensing tip.

3. Position the dispensing tip on the cat's back between the shoulder blades. Use the dispensing tip of the tube to part the cat's hair so that the product will be applied at skin level. Squeeze applicator, applying entire contents in a single spot on the animal's skin. Separate treated cat from other (dogs and cats) (pets) for 24 hours after treatment has been applied.
4. Repeat every month.

PRODUCT NAME contains Fipronil and the insect growth regulatory (IGR) (S)-Methoprene. PRODUCT NAME effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, chewing lice and mosquitoes.

PRODUCT NAME can also be used for the treatment and control of mosquitoes, and flea, tick and chewing lice infestations on breeding, pregnant and lactating queens.

FREQUENCY OF APPLICATION

When used monthly, PRODUCT NAME completely breaks the flea life cycle and controls tick and chewing lice infestations. Research demonstrates that PRODUCT NAME kills adult fleas, flea eggs, and flea larvae for up to six weeks. PRODUCT NAME also prevents development of all flea stages for up to six weeks. PRODUCT NAME kills ticks for a least one month. A once monthly application is recommended where tick control is needed. Although PRODUCT NAME can control fleas for up to six weeks, if there is a high risk of reinfestation or if the pet has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

With a monthly application of PRODUCT NAME kills mosquitoes within 24 hours for up to 14 days and within 48 hours for up to 28 days.

PRODUCT NAME remains effective even after bathing, water immersion, or exposure to sunlight. Avoid contact with treated area until dry. Do not reapply PRODUCT NAME for 30 days.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

STORAGE. Store unused product in original container, out of reach of children and animals.

PESTICIDE DISPOSAL. If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

CONTAINER DISPOSAL. If empty: Do not reuse this container. Place in trash or offer for recycling if available.

For more information call our (flea and tick) experts at 1-800-275-1414 (weekdays, 9 am – 5 pm E.S.T.)

INDIVIDUAL TUBE TEXT

Product Name

Active Ingredients:

Fipronil 9.8%, (S)-Methoprene 11.8%

Keep Out of Reach of Children

Caution

Read accompanying label before use

EPA Reg. No. 2596-RAA

EPA Est. No.

Product Name can also be used for the treatment and control of mosquitoes, and flea, tick and chewing lice infestations on breeding, pregnant and lactating queens.

Product Name contains Fipronil and the insect growth regulator (IGR) (S)-Methoprene. Product Name effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, chewing lice and mosquitoes.

Stops and prevents infestations

Kills adult fleas, flea eggs, and flea larvae

Prevents all flea stages (eggs, larvae, pupae) from developing

Kills fleas which may cause flea allergy dermatitis

Kills all stages of Deer Ticks (which may carry Lyme disease), Brown Dog Ticks, American Dog Ticks, and Lone Star Ticks

Kills mosquitoes

Prevents and controls reinfestations

Rapidly eliminates infestations with chewing lice

Can also be used on breeding, pregnant and lactating queens

Fast-acting

Long-lasting

Waterproof

Convenient to use

[Adult Fleas]

Kills Fleas (that may transmit tapeworms) (for) (28 days) (30 days) (1 month) (4 weeks) (on cats)

Kills (Adult) Fleas (for up to 3 months)

Kills fleas that may cause (flea allergy dermatitis) (and) (flea bite anemia) (for) (28 days) (30 days) (1 month) (4 weeks) (3 months) (on cats)

Kills newly emerged adult Fleas before they lay eggs

If there is a high risk for flea reinfestation, a once a month application may be needed

Stops existing infestations

Prevents establishment of new infestations

[Flea Eggs]

Kills Flea Eggs (and Flea Larvae) (for) (28 days) (30 days) (1 month) (4 weeks)

Prevents Flea Eggs from hatching

[Ticks]

Kills Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of) Brown Dog Ticks, American Dog Ticks, Lone Star Ticks and Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of) Deer Ticks (that may carry Lyme disease) (for) (28 days) (30 days) (1 month) (4 weeks) (on cats)

Kills all biting stages of ticks

Kills adult (brown dog) (deer) ticks, nymphs and larvae

Kills Ticks including those that may transmit Lyme disease

[Lice & Mange]

Rapidly eliminates chewing lice infestations

Aids in Control of sarcoptic mange infestations

[Multiple]

Kills Fleas, Ticks, Flea eggs, Chewing Lice, (Flea larvae)

Kills Fleas, Ticks, Flea eggs, (Flea larvae) (through contact) (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, (Flea larvae), (Chewing lice) (through contact) (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, (Flea larvae) (after contact) (for) (28 days) (30 days) (1 month) (4 weeks)

Prevents development of all flea stages for up to 3 months.

Kills adult Fleas, Flea Eggs and Larvae (for up to three months)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, (Flea larvae) (after contact) (for) (28 days) (30 days) (1 month) (4 weeks)

Controls Flea and Tick infestations (on cats) (for) (28 days) (30 days) (1 month) (4 weeks)

Provides fast, effective and convenient treatment and control of fleas, ticks, chewing lice and mosquitoes (for cats and kittens)

Helps prevent re-infestation of fleas and ticks (for) (28 days) (30 days) (1 month) (4 weeks)
Helps prevent flea and tick re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)
Kills flea eggs and flea larvae to help prevent future re-infestations
Kills all stages of the flea life cycle
Breaks the flea life cycle
Prevents all flea stages (eggs, larvae, pupae) from developing

[Mosquitoes]

Kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.
Kills Mosquitoes that may transmit West Nile virus (for) (28 days)(1 month) (4 weeks)(on cats)
Kills Mosquitoes that may transmit heartworm (for) (28 days)(1 month) (4 weeks)(on cats)

Controls flea and tick infestations

Once-a-month Flea and Tick (Prevention) (Treatment) (Control) (Solution)
Monthly Flea and Tick (Prevention) (Treatment) (Control) (Solution)
(28 day) (30 day) (1 month) (4 week) Flea and Tick (Prevention) (Treatment) (Control)
(Solution)

Prevents flea eggs from developing into biting adults (for) (up to) (30 days) (1 month) (4 weeks)
Gentle protection for cats (and kittens)

Quick drying (formula)

Dries quickly

Stays on and doesn't rub off

Spreads with cat's natural skin oils

Kills fleas for 30 days (1 month) (4 weeks)

Stops and prevents infestations

Prevents re-infestation

Prevents and controls re-infestation(s)

Rapidly eliminates fleas

Fast acting

Long lasting

Effective and convenient topical treatment

Kills fleas (and ticks) through (after) contact

(With) patented applicator

(With) patent pending applicator

Waterproof

Easy spot on topical applicator

Do not reapply product for 30 days

Remains effective even after bathing, water immersion, or exposure to sunlight

(Product Name) remains effective even after bathing, water immersion, or exposure to sunlight.

Avoid contact with treated area until dry.

Can also be used on breeding, pregnant and lactating queens

Convenient to use

Contains Fipronil and the insect growth regulator (IGR) (S)-Methoprene. (product name)
effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles,
and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting

activity against fleas, ticks and chewing lice.

New (Formula) *(claim to be removed after 6 months)*

Contains Fipronil and (S)-Methoprene (, the active ingredients used in Frontline Plus®).
(Brand name) is not manufactured by or distributed by Merial. Frontline Plus® is a registered trademark of Merial.

Compare to Frontline Plus®

For cats and kittens 8 weeks of age or older
Specially formulated for cats and kittens

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

1st dose, 2nd dose, 3rd dose (Xth dose)

First month, second month, third month (Xth month)

Value pack

(X) month supply

(X) monthly treatment(s)

Fragrance-free

Unscented

Convenient (easy to use) applicator

X Pro-cision Flo® Applicator(s)

With Pro-cision Flo® Applicator

Featuring Pro-cision Flo® Applicator (for easy application)

Direct to your cat's skin

Easy (simple) to use (handle) (apply)

After application, the treated area may appear wet (or) (oily) for up to 24 hours

You may bathe your cat 48 hours after application

To help remind you when you last applied treatment, simply write in the date when each dose is applied:

First Dose _____

Second Dose _____

Third Dose _____

Xth Dose _____

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation

Hartz® Reference # 131

Alternate Brand Names

Hartz® UltraGuard Plus® Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)
Hartz® UltraGuard Pro® Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)
Hartz® UltraGuard Max™ Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)

Hartz® InControl Advanced® Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)
Hartz® InControl Max™ Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)

Revo™ Advanced™ Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)

Hartz® Revo Advanced™ Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)

Hartz® Pro Force™ Dual Action Topical Treatment for Cats (& Kittens)
Hartz® FieldForce™ Dual Action Topical Treatment for Cats (& Kittens)
Hartz® First Defense™ Dual Action Topical Treatment for Cats (& Kittens)

Hartz® Pro Force™ for Cats (& Kittens)
Hartz® FieldForce™ for Cats (& Kittens)
Hartz® First Defense™ for Cats (& Kittens)
Hartz® UltraGuard Plus® Flea (and) (&) Tick Topical Solution for Cats (& Kittens)
Hartz® UltraGuard Pro® Flea (and) (&) Tick Topical Solution for Cats (& Kittens)
Hartz® UltraGuard Max™ Flea (and) (&) Tick Topical Solution for Cats (& Kittens)
Hartz® InControl Advanced® Flea (and) (&) Tick Topical Solution for Cats (& Kittens)
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Revo Advanced™ Flea (and) (&) Tick Topical Solution for Cats (& Kittens)
Hartz® Revo Advanced™ Flea (and) (&) Tick Topical Solution for Cats (& Kittens)
Hartz® Pro Force™ Dual Action Topical Solution for Cats (& Kittens)
Hartz® FieldForce™ Dual Action Topical Solution for Cats (& Kittens)
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FieldForce™ Dual Action Topical Treatment for Cats (& Kittens)
First Defense™ Dual Action Topical Treatment for Cats (& Kittens)
FieldForce™ for Cats (& Kittens)
First Defense™ for Cats (& Kittens)
FieldForce™ Dual Action Topical Solution for Cats (& Kittens)
First Defense™ Dual Action Topical Solution for Cats (& Kittens)

ACTIVE INGREDIENTS:

Fipronil.....9.80%
(S)-Methoprene.....11.80%

OTHER INGREDIENTS78.40%

TOTAL100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for additional precautionary statements.

NET CONTENTS: Contains (*number*) tubes, each ___ fl. oz. (___ ml)

EPA Reg. No. 2596-RAA
EPA Est. No.

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.
Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION.

Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling.

HAZARDS TO DOMESTIC ANIMALS.

For external use only. Do not use on kittens under 8 weeks of age. Individual sensitivities, while rare, may occur after using any pesticide product. Pets may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian immediately. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged animals. Call 1-800-275-1414 for 24-hour assistance.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE: Do not use or store near heat or open flame.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents, you may call 1-800-275-1414.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Flush eyes with plenty of water. Call a doctor if irritation persists.

IF ON SKIN OR CLOTHING: Wash with plenty of soap and water. Get medical attention if irritation persists.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR PET READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.

To kill fleas, all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks [which may carry Lyme disease], chewing lice and mosquitoes, apply to cats and kittens [8 weeks or older] as follows:

[USE DIRECTIONS HERE]

(The application steps below may optionally be numbered or bulleted to clarify the order, depending on the final physical layout of the label)

[Option 1 capped tube]

Remove one applicator tube from the package and hold in an upright position (pointed away from your face). Pull off cap. Turn the cap around and place on top of tube. Simply press cap down to break the seal of the tube. Remove cap carefully. Position the tip of the tube on the cat's back between the shoulder blades. Use the tip of the tube to part the cat's hair so that the product will be applied at skin level. (Do not bathe your cat 48 hours prior to application.) Squeeze applicator, applying entire contents in a single spot on the animal's skin. Separate treated cat from other (dogs and cats) (pets) for 24 hours after treatment has been applied. Repeat every month.

[Option 2 applicator tube]

Remove one applicator tube from the package and hold in an upright position pointed away from your face. Twist dispensing tip clockwise about ½ turn while pushing down to break the tube's seal. Do not remove the dispensing tip. Position the dispensing tip on the cat's back between the shoulder blades. Use the dispensing tip of the tube to part the cat's hair so that the product will be applied at skin level. (Do not bathe your cat 48 hours prior to application.) Squeeze applicator, applying entire contents in a single spot on the animal's skin. Separate treated cat from other (dogs and cats) (pets) for 24 hours after treatment has been applied. Repeat every month.

PRODUCT NAME contains Fipronil and the insect growth regulatory (IGR) (S)-Methoprene. PRODUCT NAME effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, chewing lice and mosquitoes.

PRODUCT NAME can also be used for the treatment and control of mosquitoes, and flea, tick and chewing lice infestations on breeding, pregnant and lactating queens.

FREQUENCY OF APPLICATION

When used monthly, PRODUCT NAME completely breaks the flea life cycle and controls tick and chewing lice infestations. Research demonstrates that PRODUCT NAME kills adult fleas, flea eggs, and flea larvae for up to six weeks. PRODUCT NAME also prevents development of all flea stages for up to six weeks. PRODUCT NAME kills ticks for a least one month. A once monthly application is recommended where tick control is needed. Although PRODUCT NAME can control fleas for up to six weeks, if there is a high risk of reinfestation or if the pet has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

With a monthly application of PRODUCT NAME kills mosquitoes within 24 hours for up to 14 days and within 48 hours for up to 28 days.

PRODUCT NAME remains effective even after bathing, water immersion, or exposure to sunlight. Avoid contact with treated area until dry. Do not reapply PRODUCT NAME for 30 days.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

STORAGE. Store unused product in original container, out of reach of children and animals.

PESTICIDE DISPOSAL. If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

CONTAINER DISPOSAL. If empty: Do not reuse this container. Place in trash or offer for recycling if available.

For more information call our (flea and tick) experts at 1-800-275-1414 (weekdays, 9 am – 5 pm E.S.T.)

INDIVIDUAL TUBE TEXT

Product Name

Active Ingredients:

Fipronil 9.8%, (S)-Methoprene 11.8%

Keep Out of Reach of Children

Caution

Read accompanying label before use

EPA Reg. No. 2596-RAA

EPA Est. No.

Product Name can also be used for the treatment and control of mosquitoes, and flea, tick and chewing lice infestations on breeding, pregnant and lactating queens.

Product Name contains Fipronil and the insect growth regulator (IGR) (S)-Methoprene. Product Name effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, chewing lice and mosquitoes.

Stops and prevents infestations

Kills adult fleas, flea eggs, and flea larvae

Prevents all flea stages (eggs, larvae, pupae) from developing

Kills fleas which may cause flea allergy dermatitis

Kills all stages of Deer Ticks (which may carry Lyme disease), Brown Dog Ticks, American Dog Ticks, and Lone Star Ticks

Kills mosquitoes

Prevents and controls reinfestations

Rapidly eliminates infestations with chewing lice

Can also be used on breeding, pregnant and lactating queens

Fast-acting

Long-lasting

Waterproof

Convenient to use

[Adult Fleas]

Kills Fleas (that may transmit tapeworms) (for) (28 days) (30 days) (1 month) (4 weeks) (on cats)

Kills (Adult) Fleas (for up to 3 months)

Kills fleas that may cause (flea allergy dermatitis) (and) (flea bite anemia) (for) (28 days) (30 days) (1 month) (4 weeks) (3 months) (on cats)

Kills newly emerged adult Fleas before they lay eggs

If there is a high risk for flea reinfestation, a once a month application may be needed

Stops existing infestations
Prevents establishment of new infestations

[Flea Eggs]

Kills Flea Eggs (and Flea Larvae) (for) (28 days) (30 days) (1 month) (4 weeks)
Prevents Flea Eggs from hatching

[Ticks]

Kills Ticks (for) (28 days) (30 days) (1 month) (4 weeks)
Kills (all stages of) Brown Dog Ticks, American Dog Ticks, Lone Star Ticks and Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)
Kills (all stages of) Deer Ticks (that may carry Lyme disease) (for) (28 days) (30 days) (1 month) (4 weeks) (on cats)
Kills all biting stages of ticks
Kills adult (brown dog) (deer) ticks, nymphs and larvae
Kills Ticks including those that may transmit Lyme disease

[Lice & Mange]

Rapidly eliminates chewing lice infestations
Aids in Control of sarcoptic mange infestations

[Multiple]

Kills Fleas, Ticks, Flea eggs, Chewing Lice, (Flea larvae)
Kills Fleas, Ticks, Flea eggs, (Flea larvae) (through contact) (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea Eggs, (Flea larvae), (Chewing lice) (through contact) (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea eggs, (Flea larvae) (after contact) (for) (28 days) (30 days) (1 month) (4 weeks)
Prevents development of all flea stages for up to 3 months.
Kills adult Fleas, Flea Eggs and Larvae (for up to three months)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, (Flea larvae) (after contact) (for) (28 days) (30 days) (1 month) (4 weeks)
Controls Flea and Tick infestations (on cats) (for) (28 days) (30 days) (1 month) (4 weeks)
Provides fast, effective and convenient treatment and control of fleas, ticks, chewing lice and mosquitoes (for cats and kittens)

Helps prevent re-infestation of fleas and ticks (for) (28 days) (30 days) (1 month) (4 weeks)
Helps prevent flea and tick re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)
Kills flea eggs and flea larvae to help prevent future re-infestations
Kills all stages of the flea life cycle
Breaks the flea life cycle
Prevents all flea stages (eggs, larvae, pupae) from developing

[Mosquitoes]

Kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.

Kills Mosquitoes that may transmit West Nile virus (for) (28 days)(1 month) (4 weeks)(on cats)

Kills Mosquitoes that may transmit heartworm (for) (28 days)(1 month) (4 weeks)(on cats)

Controls flea and tick infestations

Once-a month Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Monthly Flea and Tick (Prevention) (Treatment) (Control) (Solution)

(28 day) (30 day) (1 month) (4 week) Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Prevents flea eggs from developing into biting adults (for) (up to) (30 days) (1 month) (4 weeks)

Gentle protection for cats (and kittens)

Quick drying (formula)

Dries quickly

Stays on and doesn't rub off

Spreads with cat's natural skin oils

Kills fleas for 30 days (1 month) (4 weeks)

Stops and prevents infestations

Prevents re-infestation

Prevents and controls re-infestation(s)

Rapidly eliminates fleas

Fast acting

Long lasting

Effective and convenient topical treatment

Kills fleas (and ticks) through (after) contact

(With) patented applicator

(With) patent pending applicator

Waterproof

Easy spot on topical applicator

Do not reapply product for 30 days

Remains effective even after bathing, water immersion, or exposure to sunlight

(Product Name) remains effective even after bathing, water immersion, or exposure to sunlight.

Avoid contact with treated area until dry.

Can also be used on breeding, pregnant and lactating queens

Convenient to use

Contains Fipronil and the insect growth regulator (IGR) (S)-Methoprene. (product name).
effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles,
and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting
activity against fleas, ticks and chewing lice.

New (Formula) (*claim to be removed after 6 months*)

Contains Fipronil and (S)-Methoprene (, the active ingredients used in Frontline Plus®).

(Brand name) is not manufactured by or distributed by Merial. Frontline Plus® is a registered trademark of Merial.

Compare to Frontline Plus®

For cats and kittens 8 weeks of age or older
Specially formulated for cats and kittens

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

1st dose, 2nd dose, 3rd dose (Xth dose)

First month, second month, third month (Xth month)

X-pack

X-tubes

Value pack

X month supply

X monthly treatment(s)

Fragrance-free

Unscented

Fresh (scent) (fragrance)

Powder (scent) (fragrance)

Pleasant (scent) (fragrance)

Spring Fresh Scent

Convenient (easy to use) applicator

X Pro-cision Flo® Applicator(s)

With Pro-cision Flo® Applicator

Featuring Pro-cision Flo® Applicator (for easy application)

Direct to your cat's skin

Easy (simple) to use (handle) (apply)

(Featuring the) (with) EZC™ tube

(Featuring the) (with) EZ2C™ tube

(Featuring the) (with) EZView™ tube

(Featuring the) (with) EZView™ tube

(Featuring the) (with) Clearview™ tube

(Featuring the) (with) Clearview™ tube

(Clearview™) (EZC™) (EZ2C™) (EZView™) tube (visually) ensures all product has been dispensed

(Clearview™) (EZC™) (EZ2C™) (EZView™) tubes give you the assurance all the product has been applied

After application, the treated area may appear wet (or) (oily) for up to 24 hours

You may bathe your cat 48 hours after application

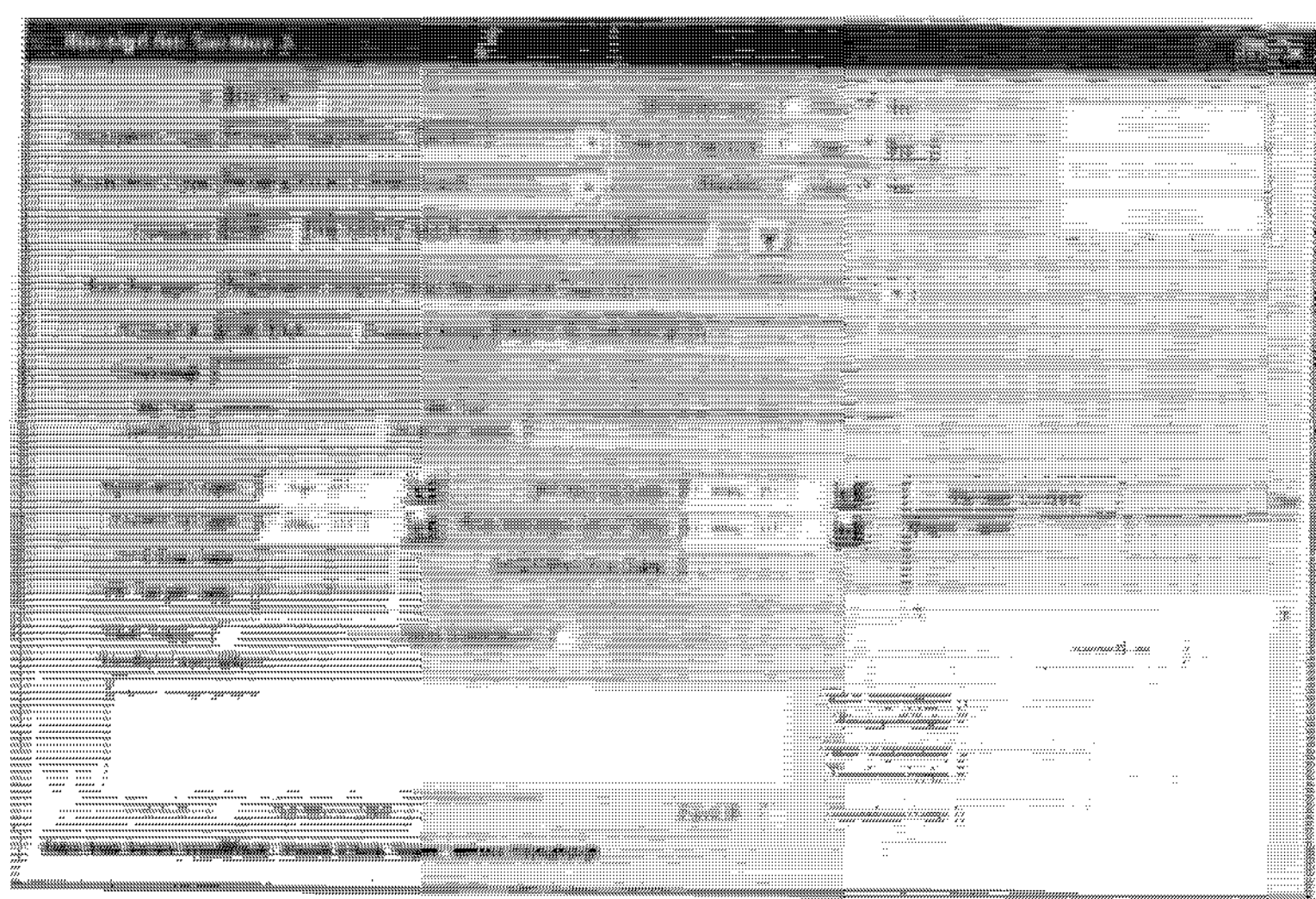
To help remind you when you last applied treatment, simply write in the date when each dose is applied:

First Dose _____

Second Dose _____

Third Dose _____
Xth Dose _____

Hartz[®] and other trademarks are trademarks of The Hartz Mountain Corporation



Resubmission



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May 2, 2012

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

LANCE HEMSARTH
THE HARTZ MOUNTAIN CORPORATION
400 PLAZA DRIVE
SECAUCUS, NJ 07094-

PRODUCT NAME: HARTZ REFERENCE #131
COMPANY NAME: THE HARTZ MOUNTAIN CORPORATION
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 2596-RAA
EPA RECEIPT DATE: 05/01/12

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 10, at (703) 305-6701.

Sincerely,

A handwritten signature in black ink, appearing to read "Seyn", is positioned above the typed name of the sender.

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

Fee for Service

{916104t~

This package includes the following

☐ New Registration

☒ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: _____

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr.

10

Receipt No.

S-

916104

EPA File Symbol/Reg. No.

2596-RAA

Pin-Punch Date:

4/30/2012



This item is NOT subject to FFS action.

Action Code:

Requested:

Granted:

Amount Due: \$ _____

Parent/Child Decisions:

☐ Inert Cleared for Intended Use



Uncleared Inert in Product

Reviewer: _____

[Signature]

Date: _____

5/2/12

Remarks:

Resubmission



THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094-3688 • 201/271-4800

April 27, 2012

Document Processing Desk
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: **Mr. Richard Gebken (PM # 10)**

RE: HARTZ REF #128, EPA Reg. No. 2596-RAG
HARTZ REF #129, EPA Reg. No. 2596-RAU
HARTZ REF #130, EPA Reg. No. 2596-RAL
HARTZ REF #131, EPA Reg. No. 2596-RAA

Dear Mr. Gebken:

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688 is filing modified labels based on the feedback from Rosalind Gross and her review of the CRP data for the above listed registrations. Changes were made only to the directions for use sections in order to match the instructions for use in the child resistant packaging testing labels.

These master labels replace the current labels that were submitted for the above listed registrations. Please find enclosed 3 copies of each Master Label.

If you have any questions or need any additional information, please feel free to call me at (201) 271-4800, ext. 7302 or smcneear@hartz.com.

Sincerely,

A handwritten signature in black ink, appearing to read "Sean McNear". The signature is fluid and cursive, with a large, stylized initial "S".

Sean McNear
Director Regulatory Affairs

Enclosures



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 2596-RAA	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Hartz Ref. 131	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) The Hartz Mountain Corporation 400 Plaza Drive, Secaucus, NJ 07094 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

I label change based on the feedback from Rosalind Gross. Changes made to the master label directions for use to be exactly the same as the instructions for the child resistant packaging (CRP) test.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
					<input type="checkbox"/> Glass
					<input type="checkbox"/> Paper
					<input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name Sean McNear	Title Director Reg. Affairs	Telephone No. (Include Area Code) 201-271-4800
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Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

8. Date Application Received
(Stamped)

2. Signature 	3. Title Director Regulatory Affairs	8. Date Application Received (Stamped)
4. Typed Name Sean McNear	5. Date April 27, 2012	

Hartz® Reference # 131

Alternate Brand Names

Hartz® UltraGuard Plus® Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)
Hartz® UltraGuard Pro® Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)
Hartz® UltraGuard Max™ Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)

Hartz® InControl Advanced® Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)
Hartz® InControl Max™ Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)

Revo™ Advanced™ Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)

Hartz® Revo Advanced™ Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)

Hartz® Pro Force™ Dual Action Topical Treatment for Cats (& Kittens)
Hartz® FieldForce™ Dual Action Topical Treatment for Cats (& Kittens)
Hartz® First Defense™ Dual Action Topical Treatment for Cats (& Kittens)

Hartz® Pro Force™ for Cats (& Kittens)
Hartz® FieldForce™ for Cats (& Kittens)
Hartz® First Defense™ for Cats (& Kittens)
Hartz® UltraGuard Plus® Flea (and) (&) Tick Topical Solution for Cats (& Kittens)
Hartz® UltraGuard Pro® Flea (and) (&) Tick Topical Solution for Cats (& Kittens)
Hartz® UltraGuard Max™ Flea (and) (&) Tick Topical Solution for Cats (& Kittens)
Hartz® InControl Advanced® Flea (and) (&) Tick Topical Solution for Cats (& Kittens)
Hartz® InControl Max™ Flea (and) (&) Tick Topical Solution for Cats (& Kittens)
Revo Advanced™ Flea (and) (&) Tick Topical Solution for Cats (& Kittens)
Hartz® Revo Advanced™ Flea (and) (&) Tick Topical Solution for Cats (& Kittens)
Hartz® Pro Force™ Dual Action Topical Solution for Cats (& Kittens)
Hartz® FieldForce™ Dual Action Topical Solution for Cats (& Kittens)
Hartz® First Defense™ Dual Action Topical Solution for Cats (& Kittens)
FieldForce™ Dual Action Topical Treatment for Cats (& Kittens)
First Defense™ Dual Action Topical Treatment for Cats (& Kittens)
FieldForce™ for Cats (& Kittens)
First Defense™ for Cats (& Kittens)
FieldForce™ Dual Action Topical Solution for Cats (& Kittens)
First Defense™ Dual Action Topical Solution for Cats (& Kittens)

ACTIVE INGREDIENTS:

Fipronil.....	9.80%
(S)-Methoprene.....	11.80%
OTHER INGREDIENTS	78.40%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for additional precautionary statements.

NET CONTENTS: Contains *(number)* tubes, each ___ fl. oz. (___ ml)

EPA Reg. No. 2596-RAA
EPA Est. No.

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.
Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION.

Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling.

HAZARDS TO DOMESTIC ANIMALS.

For external use only. Do not use on kittens under 8 weeks of age. Individual sensitivities, while rare, may occur after using any pesticide product. Pets may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian immediately. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged animals. Call 1-800-275-1414 for 24-hour assistance.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE: Do not use or store near heat or open flame.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents, you may call 1-800-275-1414.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Flush eyes with plenty of water. Call a doctor if irritation persists.

IF ON SKIN OR CLOTHING: Wash with plenty of soap and water. Get medical attention if irritation persists.

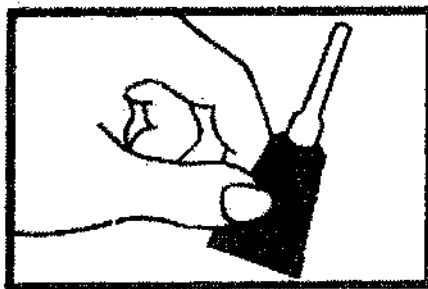
DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. **TO PREVENT HARM TO YOU AND YOUR PET READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.**

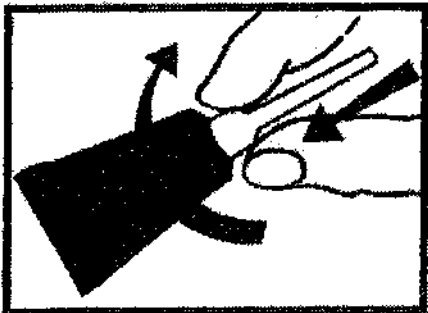
To kill fleas, all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks [which may carry Lyme disease], chewing lice and mosquitoes, apply to cats and kittens [8 weeks or older] as follows:

[USE DIRECTIONS HERE]

(The application steps below may optionally be numbered or bulleted to clarify the order, depending on the final physical layout of the label)



1 Remove one applicator tube from the package and hold in an upright position pointed away from your face.



2 Twist dispensing tip clockwise about $\frac{1}{2}$ turn while pushing down to break the tube's seal. Do not remove the dispensing tip.

3. Position the dispensing tip on the cat's back between the shoulder blades. Use the dispensing tip of the tube to part the cat's hair so that the product will be applied at skin level. Squeeze applicator, applying entire contents in a single spot on the animal's skin. Separate treated cat from other (dogs and cats) (pets) for 24 hours after treatment has been applied.
4. Repeat every month.

PRODUCT NAME contains Fipronil and the insect growth regulatory (IGR) (S)-Methoprene. PRODUCT NAME effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, chewing lice and mosquitoes.

PRODUCT NAME can also be used for the treatment and control of mosquitoes, and flea, tick and chewing lice infestations on breeding, pregnant and lactating queens.

FREQUENCY OF APPLICATION

When used monthly, PRODUCT NAME completely breaks the flea life cycle and controls tick and chewing lice infestations. Research demonstrates that PRODUCT NAME kills adult fleas, flea eggs, and flea larvae for up to six weeks. PRODUCT NAME also prevents development of all flea stages for up to six weeks. PRODUCT NAME kills ticks for a least one month. A once monthly application is recommended where tick control is needed. Although PRODUCT NAME can control fleas for up to six weeks, if there is a high risk of reinfestation or if the pet has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

With a monthly application of PRODUCT NAME kills mosquitoes within 24 hours for up to 14 days and within 48 hours for up to 28 days.

PRODUCT NAME remains effective even after bathing, water immersion, or exposure to sunlight. Avoid contact with treated area until dry. Do not reapply PRODUCT NAME for 30 days.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

STORAGE. Store unused product in original container, out of reach of children and animals.

PESTICIDE DISPOSAL. If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

CONTAINER DISPOSAL. If empty: Do not reuse this container. Place in trash or offer for recycling if available.

For more information call our (flea and tick) experts at 1-800-275-1414 (weekdays, 9 am – 5 pm E.S.T.)

INDIVIDUAL TUBE TEXT

Product Name

Active Ingredients:

Fipronil 9.8%, (S)-Methoprene 11.8%

Keep Out of Reach of Children

Caution

Read accompanying label before use

EPA Reg. No. 2596-RAA

EPA Est. No.

Product Name can also be used for the treatment and control of mosquitoes, and flea, tick and chewing lice infestations on breeding, pregnant and lactating queens.

Product Name contains Fipronil and the insect growth regulator (IGR) (S)-Methoprene. Product Name effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, chewing lice and mosquitoes.

Stops and prevents infestations

Kills adult fleas, flea eggs, and flea larvae

Prevents all flea stages (eggs, larvae, pupae) from developing

Kills fleas which may cause flea allergy dermatitis

Kills all stages of Deer Ticks (which may carry Lyme disease), Brown Dog Ticks, American Dog Ticks, and Lone Star Ticks

Kills mosquitoes

Prevents and controls reinfestations

Rapidly eliminates infestations with chewing lice

Can also be used on breeding, pregnant and lactating queens

Fast-acting

Long-lasting

Waterproof

Convenient to use

[Adult Fleas]

Kills Fleas (that may transmit tapeworms) (for) (28 days) (30 days) (1 month) (4 weeks) (on cats)

Kills (Adult) Fleas (for up to 3 months)

Kills fleas that may cause (flea allergy dermatitis) (and) (flea bite anemia) (for) (28 days) (30 days) (1 month) (4 weeks) (3 months) (on cats)

Kills newly emerged adult Fleas before they lay eggs

If there is a high risk for flea reinfestation, a once a month application may be needed

Stops existing infestations

Prevents establishment of new infestations

[Flea Eggs]

Kills Flea Eggs (and Flea Larvae) (for) (28 days) (30 days) (1 month) (4 weeks)

Prevents Flea Eggs from hatching

[Ticks]

Kills Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of) Brown Dog Ticks, American Dog Ticks, Lone Star Ticks and Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of) Deer Ticks (that may carry Lyme disease) (for) (28 days) (30 days) (1 month) (4 weeks) (on cats)

Kills all biting stages of ticks

Kills adult (brown dog) (deer) ticks, nymphs and larvae

Kills Ticks including those that may transmit Lyme disease

[Lice & Mange]

Rapidly eliminates chewing lice infestations

Aids in Control of sarcoptic mange infestations

[Multiple]

Kills Fleas, Ticks, Flea eggs, Chewing Lice, (Flea larvae)

Kills Fleas, Ticks, Flea eggs, (Flea larvae) (through contact) (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, (Flea larvae), (Chewing lice) (through contact) (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, (Flea larvae) (after contact) (for) (28 days) (30 days) (1 month) (4 weeks)

Prevents development of all flea stages for up to 3 months.

Kills adult Fleas, Flea Eggs and Larvae (for up to three months)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, (Flea larvae) (after contact) (for) (28 days) (30 days) (1 month) (4 weeks)

Controls Flea and Tick infestations (on cats) (for) (28 days) (30 days) (1 month) (4 weeks)

Provides fast, effective and convenient treatment and control of fleas, ticks, chewing lice and mosquitoes (for cats and kittens)

Helps prevent re-infestation of fleas and ticks (for) (28 days) (30 days) (1 month) (4 weeks)
Helps prevent flea and tick re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)
Kills flea eggs and flea larvae to help prevent future re-infestations
Kills all stages of the flea life cycle
Breaks the flea life cycle
Prevents all flea stages (eggs, larvae, pupae) from developing

[Mosquitoes]

Kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.
Kills Mosquitoes that may transmit West Nile virus (for) (28 days)(1 month) (4 weeks)(on cats)
Kills Mosquitoes that may transmit heartworm (for) (28 days)(1 month) (4 weeks)(on cats)

Controls flea and tick infestations
Once-a month Flea and Tick (Prevention) (Treatment) (Control) (Solution)
Monthly Flea and Tick (Prevention) (Treatment) (Control) (Solution)
(28 day) (30 day) (1 month) (4 week) Flea and Tick (Prevention) (Treatment) (Control)
(Solution)
Prevents flea eggs from developing into biting adults (for) (up to) (30 days) (1 month) (4 weeks)
Gentle protection for cats (and kittens)
Quick drying (formula)
Dries quickly
Stays on and doesn't rub off
Spreads with cat's natural skin oils
Kills fleas for 30 days (1 month) (4 weeks)
Stops and prevents infestations
Prevents re-infestation
Prevents and controls re-infestation(s)
Rapidly eliminates fleas
Fast acting
Long lasting
Effective and convenient topical treatment
Kills fleas (and ticks) through (after) contact
(With) patented applicator
(With) patent pending applicator
Waterproof
Easy spot on topical applicator
Do not reapply product for 30 days
Remains effective even after bathing, water immersion, or exposure to sunlight
(Product Name) remains effective even after bathing, water immersion, or exposure to sunlight.
Avoid contact with treated area until dry.
Can also be used on breeding, pregnant and lactating queens
Convenient to use
Contains Fipronil and the insect growth regulator (IGR) (S)-Methoprene. (product name)
effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles,
and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting

activity against fleas, ticks and chewing lice.

New (Formula) *(claim to be removed after 6 months)*

Contains Fipronil and (S)-Methoprene (, the active ingredients used in Frontline Plus®).
(Brand name) is not manufactured by or distributed by Merial. Frontline Plus® is a registered trademark of Merial.

Compare to Frontline Plus®

For cats and kittens 8 weeks of age or older
Specially formulated for cats and kittens

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

1st dose, 2nd dose, 3rd dose (Xth dose)

First month, second month, third month (Xth month)

Value pack

(X) month supply

(X) monthly treatment(s)

Fragrance-free

Unscented

Convenient (easy to use) applicator

X Pro-cision Flo® Applicator(s)

With Pro-cision Flo® Applicator

Featuring Pro-cision Flo® Applicator (for easy application)

Direct to your cat's skin

Easy (simple) to use (handle) (apply)

After application, the treated area may appear wet (or) (oily) for up to 24 hours

You may bathe your cat 48 hours after application

To help remind you when you last applied treatment, simply write in the date when each dose is applied:

First Dose _____

Second Dose _____

Third Dose _____

Xth Dose _____

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation

Hartz® Reference # 131

Alternate Brand Names

Hartz® UltraGuard Plus® Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)
Hartz® UltraGuard Pro® Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)
Hartz® UltraGuard Max™ Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)

Hartz® InControl Advanced® Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)
Hartz® InControl Max™ Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)

Revo™ Advanced™ Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)

Hartz® Revo Advanced™ Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)

Hartz® Pro Force™ Dual Action Topical Treatment for Cats (& Kittens)
Hartz® FieldForce™ Dual Action Topical Treatment for Cats (& Kittens)
Hartz® First Defense™ Dual Action Topical Treatment for Cats (& Kittens)

Hartz® Pro Force™ for Cats (& Kittens)
Hartz® FieldForce™ for Cats (& Kittens)
Hartz® First Defense™ for Cats (& Kittens)
Hartz® UltraGuard Plus® Flea (and) (&) Tick Topical Solution for Cats (& Kittens)
Hartz® UltraGuard Pro® Flea (and) (&) Tick Topical Solution for Cats (& Kittens)
Hartz® UltraGuard Max™ Flea (and) (&) Tick Topical Solution for Cats (& Kittens)
Hartz® InControl Advanced® Flea (and) (&) Tick Topical Solution for Cats (& Kittens)
Hartz® InControl Max™ Flea (and) (&) Tick Topical Solution for Cats (& Kittens)
Revo Advanced™ Flea (and) (&) Tick Topical Solution for Cats (& Kittens)
Hartz® Revo Advanced™ Flea (and) (&) Tick Topical Solution for Cats (& Kittens)
Hartz® Pro Force™ Dual Action Topical Solution for Cats (& Kittens)
Hartz® FieldForce™ Dual Action Topical Solution for Cats (& Kittens)
Hartz® First Defense™ Dual Action Topical Solution for Cats (& Kittens)
FieldForce™ Dual Action Topical Treatment for Cats (& Kittens)
First Defense™ Dual Action Topical Treatment for Cats (& Kittens)
FieldForce™ for Cats (& Kittens)
First Defense™ for Cats (& Kittens)
FieldForce™ Dual Action Topical Solution for Cats (& Kittens)
First Defense™ Dual Action Topical Solution for Cats (& Kittens)

ACTIVE INGREDIENTS:

Fipronil.....	9.30%
(S)-Methoprene.....	11.80%
OTHER INGREDIENTS	78.40%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for additional precautionary statements.

NET CONTENTS: Contains (*number*) tubes, each __ fl. oz. (__ ml)

EPA Reg. No. 2596-RAA
EPA Est. No.

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.
Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION.

Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling.

HAZARDS TO DOMESTIC ANIMALS.

For external use only. Do not use on kittens under 8 weeks of age. Individual sensitivities, while rare, may occur after using any pesticide product. Pets may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian immediately. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged animals. Call 1-800-275-1414 for 24-hour assistance.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE: Do not use or store near heat or open flame.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents, you may call 1-800-275-1414.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Flush eyes with plenty of water. Call a doctor if irritation persists.

IF ON SKIN OR CLOTHING: Wash with plenty of soap and water. Get medical attention if irritation persists.

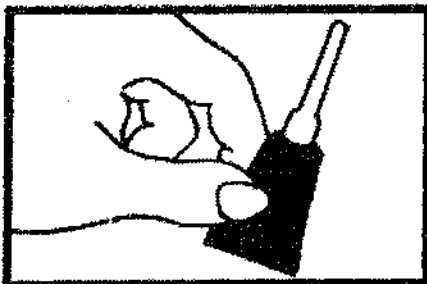
DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. **TO PREVENT HARM TO YOU AND YOUR PET READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.**

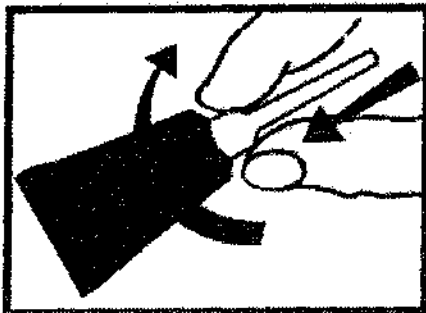
To kill fleas, all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks [which may carry Lyme disease], chewing lice and mosquitoes, apply to cats and kittens [8 weeks or older] as follows:

[USE DIRECTIONS HERE]

(The application steps below may optionally be numbered or bulleted to clarify the order, depending on the final physical layout of the label)



1 Remove one applicator tube from the package and hold in an upright position pointed away from your face.



2 Twist dispensing tip clockwise about $\frac{1}{2}$ turn while pushing down to break the tube's seal. Do not remove the dispensing tip.

3. Position the dispensing tip on the cat's back between the shoulder blades. Use the dispensing tip of the tube to part the cat's hair so that the product will be applied at skin level. Squeeze applicator, applying entire contents in a single spot on the animal's skin. Separate treated cat from other (dogs and cats) (pets) for 24 hours after treatment has been applied.
4. Repeat every month.

PRODUCT NAME contains Fipronil and the insect growth regulatory (IGR) (S)-Methoprene. PRODUCT NAME effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, chewing lice and mosquitoes.

PRODUCT NAME can also be used for the treatment and control of mosquitoes, and flea, tick and chewing lice infestations on breeding, pregnant and lactating queens.

FREQUENCY OF APPLICATION

When used monthly, PRODUCT NAME completely breaks the flea life cycle and controls tick and chewing lice infestations. Research demonstrates that PRODUCT NAME kills adult fleas, flea eggs, and flea larvae for up to six weeks. PRODUCT NAME also prevents development of all flea stages for up to six weeks. PRODUCT NAME kills ticks for a least one month. A once monthly application is recommended where tick control is needed. Although PRODUCT NAME can control fleas for up to six weeks, if there is a high risk of reinfestation or if the pet has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

With a monthly application of PRODUCT NAME kills mosquitoes within 24 hours for up to 14 days and within 48 hours for up to 28 days.

PRODUCT NAME remains effective even after bathing, water immersion, or exposure to sunlight. Avoid contact with treated area until dry. Do not reapply PRODUCT NAME for 30 days.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

STORAGE. Store unused product in original container, out of reach of children and animals.

PESTICIDE DISPOSAL. If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

CONTAINER DISPOSAL. If empty: Do not reuse this container. Place in trash or offer for recycling if available.

For more information call our (flea and tick) experts at 1-800-275-1414 (weekdays, 9 am – 5 pm E.S.T.)

INDIVIDUAL TUBE TEXT

Product Name

Active Ingredients:

Fipronil 9.8%, (S)-Methoprene 11.8%

Keep Out of Reach of Children

Caution

Read accompanying label before use

EPA Reg. No. 2596-RAA

EPA Est. No.

Product Name can also be used for the treatment and control of mosquitoes, and flea, tick and chewing lice infestations on breeding, pregnant and lactating queens.

Product Name contains Fipronil and the insect growth regulator (IGR) (S)-Methoprene. Product Name effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, chewing lice and mosquitoes.

Stops and prevents infestations

Kills adult fleas, flea eggs, and flea larvae

Prevents all flea stages (eggs, larvae, pupae) from developing

Kills fleas which may cause flea allergy dermatitis

Kills all stages of Deer Ticks (which may carry Lyme disease), Brown Dog Ticks, American Dog Ticks, and Lone Star Ticks

Kills mosquitoes

Prevents and controls reinfestations

Rapidly eliminates infestations with chewing lice

Can also be used on breeding, pregnant and lactating queens

Fast-acting

Long-lasting

Waterproof

Convenient to use

[Adult Fleas]

Kills Fleas (that may transmit tapeworms) (for) (28 days) (30 days) (1 month) (4 weeks) (on cats)

Kills (Adult) Fleas (for up to 3 months)

Kills fleas that may cause (flea allergy dermatitis) (and) (flea bite anemia) (for) (28 days) (30 days) (1 month) (4 weeks) (3 months) (on cats)

Kills newly emerged adult Fleas before they lay eggs

If there is a high risk for flea reinfestation, a once a month application may be needed

Stops existing infestations

Prevents establishment of new infestations

[Flea Eggs]

Kills Flea Eggs (and Flea Larvae) (for) (28 days) (30 days) (1 month) (4 weeks)

Prevents Flea Eggs from hatching

[Ticks]

Kills Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of) Brown Dog Ticks, American Dog Ticks, Lone Star Ticks and Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of) Deer Ticks (that may carry Lyme disease) (for) (28 days) (30 days) (1 month) (4 weeks) (on cats)

Kills all biting stages of ticks

Kills adult (brown dog) (deer) ticks, nymphs and larvae

Kills Ticks including those that may transmit Lyme disease

[Lice & Mange]

Rapidly eliminates chewing lice infestations

Aids in Control of sarcoptic mange infestations

[Multiple]

Kills Fleas, Ticks, Flea eggs, Chewing Lice, (Flea larvae)

Kills Fleas, Ticks, Flea eggs, (Flea larvae) (through contact) (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, (Flea larvae), (Chewing lice) (through contact) (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, (Flea larvae) (after contact) (for) (28 days) (30 days) (1 month) (4 weeks)

Prevents development of all flea stages for up to 3 months.

Kills adult Fleas, Flea Eggs and Larvae (for up to three months)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, (Flea larvae) (after contact) (for) (28 days) (30 days) (1 month) (4 weeks)

Controls Flea and Tick infestations (on cats) (for) (28 days) (30 days) (1 month) (4 weeks)

Provides fast, effective and convenient treatment and control of fleas, ticks, chewing lice and mosquitoes (for cats and kittens)

Helps prevent re-infestation of fleas and ticks (for) (28 days) (30 days) (1 month) (4 weeks)
Helps prevent flea and tick re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)
Kills flea eggs and flea larvae to help prevent future re-infestations
Kills all stages of the flea life cycle
Breaks the flea life cycle
Prevents all flea stages (eggs, larvae, pupae) from developing

[Mosquitoes]

Kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.
Kills Mosquitoes that may transmit West Nile virus (for) (28 days)(1 month) (4 weeks)(on cats)
Kills Mosquitoes that may transmit heartworm (for) (28 days)(1 month) (4 weeks)(on cats)

Controls flea and tick infestations
Once-a month Flea and Tick (Prevention) (Treatment) (Control) (Solution)
Monthly Flea and Tick (Prevention) (Treatment) (Control) (Solution)
(28 day) (30 day) (1 month) (4 week) Flea and Tick (Prevention) (Treatment) (Control)
(Solution)
Prevents flea eggs from developing into biting adults (for) (up to) (30 days) (1 month) (4 weeks)
Gentle protection for cats (and kittens)
Quick drying (formula)
Dries quickly
Stays on and doesn't rub off
Spreads with cat's natural skin oils
Kills fleas for 30 days (1 month) (4 weeks)
Stops and prevents infestations
Prevents re-infestation
Prevents and controls re-infestation(s)
Rapidly eliminates fleas
Fast acting
Long lasting
Effective and convenient topical treatment
Kills fleas (and ticks) through (after) contact
(With) patented applicator
(With) patent pending applicator
Waterproof
Easy spot on topical applicator
Do not reapply product for 30 days
Remains effective even after bathing, water immersion, or exposure to sunlight
(Product Name) remains effective even after bathing, water immersion, or exposure to sunlight.
Avoid contact with treated area until dry.
Can also be used on breeding, pregnant and lactating queens
Convenient to use
Contains Fipronil and the insect growth regulator (IGR) (S)-Methoprene. (product name)
effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles,
and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting

activity against fleas, ticks and chewing lice.

New (Formula) *(claim to be removed after 6 months)*

Contains Fipronil and (S)-Methoprene (, the active ingredients used in Frontline Plus®).
(Brand name) is not manufactured by or distributed by Merial. Frontline Plus® is a registered trademark of Merial.

Compare to Frontline Plus®

For cats and kittens 8 weeks of age or older
Specially formulated for cats and kittens

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

1st dose, 2nd dose, 3rd dose (Xth dose)

First month, second month, third month (Xth month)

Value pack

(X) month supply

(X) monthly treatment(s)

Fragrance-free

Unscented

Convenient (easy to use) applicator

X Pro-cision Flo® Applicator(s)

With Pro-cision Flo® Applicator

Featuring Pro-cision Flo® Applicator (for easy application)

Direct to your cat's skin

Easy (simple) to use (handle) (apply)

After application, the treated area may appear wet (or) (oily) for up to 24 hours

You may bathe your cat 48 hours after application

To help remind you when you last applied treatment, simply write in the date when each dose is applied:

First Dose _____

Second Dose _____

Third Dose _____

Xth Dose _____

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation

**ENVIRONMENTAL PROTECTION AGENCY**

Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Registration No.

2596-166

Date of Issuance:

July 9, 2012

NOTICE OF PESTICIDE:☒ Registration☐ Reregistration

(under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)

Term of Issuance:

Unconditional

Name of Pesticide Product:

Hartz ® Reference # 131**Name and Address of Registrant (include ZIP Code):**

The Hartz Mountain Corporation,
400 Plaza Drive,
Secaucus, NJ 07094

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This action is taken under the authority of section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. Registration under this section does not eliminate the need for continual reassessment of pesticides. EPA may require submission of data at any time to maintain the registration of your product.

Terms of Registration

1. EPA has registered the product listed above provided that the following change is made to the label before you release the product for shipment:
 - a. Revise the EPA Registration Number to read: "EPA Registration No 2596-166."
 - b. The Net Contents in all locations must be displayed in accordance with the description identified in the Labeling Consistency Committee's clarification. This information may be located at the following Agency web site under miscellaneous
http://www.epa.gov/opp00001/regulating/labels/label_review_faq.htm/miscellaneous. "Regarding listing net contents - Net weight or contents must be stated on a pesticide label in accordance with FIFRA (2)(q)(2)(C)(iii) and 40 CFR 156.10(a)(1)(iii). EPA interpretation of the statutory and regulatory requirements is that the label must state the total weight for the entire contents as sold and distributed. In

Signature of Approving Official:

Refer to Page 5

Richard J. Gebken, Product Manager (10)
Registration Division, Insecticide Branch

Date:

July 6, 2012

addition, the label may indicate the net weight and quantity of individual units within the carton. For example, "Net Weight 6.25 lbs. (20 - 5oz. packets)." For additional information regarding the Net Weight/Contents statement, please reference Chapter 17 of the Label Review Manual at <http://www.epa.gov/oppead1/labeling/lrm/chap-17.htm>."

- c. Under the brand name "Hartz® Reference # 131" and any other alternate brand name, add the following statement "For use ONLY on CATS 8 weeks and older" The word "CAT" the word "cat" must be the same size as the brand name.
- d. At the end of all alternate brand names containing the word "kittens" add the statement "8 weeks and older."
- e. Pictures: Hartz must place large, clear pictures of the appropriate species on the front panel.
- f. Revise the precautionary statements by replacing the sentence: "Harmful if swallowed." with "Harmful if swallowed or absorbed through the skin."
- g. Replace "Wash thoroughly with soap and water after handling." with "Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet."
- h. Replace "Individual sensitivities, while rare, may occur after using any pesticide product." with "Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately."
- i. Remove "If signs persist, or become more severe within a few days of application, consult a veterinarian immediately." This statement is incorrect and has been incorporated as part of the sensitivity statement directly above.
- j. Replace "Consult a veterinarian before using on medicated, debilitated or aged animals." with "Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals."
- k. Insert the following statement at the end of the First Aid Section:
"Have product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the Hotline number 1-800-xxx-xxx for human and veterinary health concerns, emergency medical treatment information or pesticide incidents." The xxx-xxxx must be replaced with a phone number that is available 24/7.
- l. Within the First Aid Statement, revise the "If in Eyes" statements to: "•Hold eye open and rinse slowly and gently with water for 15-20 minutes. •Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. •Call a poison control center or doctor for treatment advice." Revise the "If on Skin or Clothing:" statements to: "•Take off contaminated clothing. •Rinse skin immediately with plenty of water for 15-20 minutes. •Call a poison control center or doctor for treatment advice."
- m. Revise the following statement: "DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS." to: "DO NOT USE ON RABBITS, DOGS, PUPPIES OR OTHER ANIMALS."
- n. Remove "[USE DIRECTIONS HERE] (The application steps below may optionally be numbered or bulleted to clarify the order, depending on the final physical layout of the label)" The statement "USE DIRECTIONS HERE" are confusing, and the subsequent statement is not valid, since the SLUE testing was done using numbers only.
- o. Replace "Repeat every month" with "Reapply once per month."
- p. Within the Storage and Disposal section, revise the text within the "Disposal" section as follows: "Non-refillable container. Do not reuse or refill this container. If empty: Offer for recycling, if available. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain."
- q. INDIVIDUAL TUBE TEXT: Revise the Individual tube text as follows:
Product Name
Only for use on cats
0.017 fl oz (0.5 mL)
Contains fipronil (9.80%) and (S)-Methoprene (8.80%)
KEEP OUT OF REACH OF CHILDREN
CAUTION
See full label for additional directions
EPA Reg. No. 2596-166
- r. Remove the word "also" from the marketing claim: "Product Name can also be used for the treatment and control of mosquitoes, and flea, tick and chewing lice infestations on breeding, pregnant and lactating queens."

- s. Revise the marketing claim as follows: "Provides fast, effective and convenient treatment and control of fleas, ticks, chewing lice and mosquitoes (for cats and kittens 8 weeks or older)"
 - t. Remove the following marketing claim: "Gentle protection for cats (and kittens)" This claim is an implied safety claim, and detracts from other mandatory precautionary label language on the label.
 - u. Remove the marketing claims "Quick drying (formula)", and "Dries quickly" These claims conflict with the statement: "After application, the treated area may appear wet (or) (oily) for up to 24 hours."
 - v. The marketing claim "New (formula)" is allowed for a period of 6 months from the date of this Notice of Registration.
 - w. Remove the following statement: "Spreads with cat's natural skin oils" The Labeling Consistency Committee has deemed this misbranding under 40 CFR 156.10.
 - x. The product comparative claim must adhere to the Labeling Consistency Guidance document located at the following Agency web address: <http://www.epa.gov/pesticides/regulating/labels/pdf/mc100.pdf>.
 - y. Revise the statement "For cats and kittens 8 weeks of age or older." to: "Only for use on cats and kittens 8 weeks of age or older."
 - z. Revise the following claim: "Kills fleas that may cause (flea allergy dermatitis)(and)(flea bite anemia) (for) (28 days) (30 days) (1 month) (4 weeks) (~~3 months~~) (on cats) by removing "3 months)"
 - aa. Remove the following claim: "Prevents development of all flea stages for up to 3 months."
 - bb. Remove the following claim: "Kills adult Fleas, Flea Eggs and Larvae (for up to three months)"
 - cc. Revise the following claim: "Kills (Adult) Fleas (~~for up to 3 months~~)" by removing "for up to 3 months"
 - dd. Revise the claim: "Specially formulated for cats and kittens" to: "Formulated for cats and kittens 8 weeks of age or older."
 - ee. Replace the "(X)" in the following claims: "(X) month supply" and "(X) monthly treatment(s)" with a 3. This is the only package approved by CRP testing, and must be the only package size displayed on the label. Any other package design would require additional Child Resistant Packaging testing.
 - ff. Remove the statements: "Fragrance-free" and "Unscented" Claims about the Absence of an Ingredient: Statements or claims that express the absence of certain ingredients may be misleading statements prohibited by 40 CFR 156.10 (a)(5). These claims are examples of a true statement used in such a way as to give a false and misleading impression to the purchaser.
 - gg. Placement descriptors must be used on any future label submissions indicating the position of all text. (i.e. Front Panel, Insert, Back Panel, etc.). Future submissions will not be accepted unless these placement descriptors are identified on the label at time of submission.
 - hh. Within 30 days of this Notice of Registration, Hartz Mountain Corporation must revise the data matrix in accordance with the Companion Animal Safety Data Evaluation Report (DER) dated August 10, 2011. If the data matrix is not corrected, the claims and statements associated with this DER must be removed. In addition, there are incorrect studies cited in the data matrix for the Acute Toxicity of the product which needs to be corrected in the data matrix.
2. This registration is **time-limited and expires two years from the date this product is first released for shipment**. You must provide the Agency with a projected "release for shipment date", in writing within 30 days of the date of this Notice of Registration. The Agency will calculate the expiration date based on the projected "release for shipment date" until an actual release for shipment date is provided in writing.
 3. Only one basic confidential statement of formula (CSF) will be on file for this product at any time (i.e., no alternate formulations or minor formulation amendments will be submitted and/or approved for this product, except to allow for alternate sources of any individual inert ingredient).
 4. You must submit the following data within the timeframe described below:
Within sixteen (16) months of the date on this Notice of Registration, provide to the Agency acceptable packages for Storage stability (830.6317) data and corrosion characteristics (830.6320) data. It is recommended that observations should be made at 0, 3, 6, 9, and 12 month intervals.).
 5. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product for the quarter that begins on August 1, 2012. The quarterly reports are due two months after the end of each quarter. Please flag any Confidential Business Information (CBI) as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the Registration Division, Immediate Office (attn: Kimberly Nesci).
- The following is a list of information that must be included in the quarterly reports for each incident:
- EPA Registration Number
 - Product name (brand name)
 - Lot#
 - Where purchased: internet, store, Veterinarian
 - Active Ingredient(s)

Weight range for product
Date on which incident occurred, (mm/dd/yyyy)
State in which the incident occurred, (standard 2 letter abbreviation)
Registrant case #
Species: dog, cat, other (specify)
Breed: (as reported by pet owner)
Age: months or years
Sex: M, F, or neutered
Weight: pounds
Primary Route of Exposure: dermal, oral, other animal, inhalation, other
Body System: neurological, dermatological, GI, respiratory, ocular, other Major signs noted with separate column for each sign, using standard terminology
Time to Onset: (hours, days)
Treated by veterinarian: yes or no
First time product used: yes or no
Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
Any known precondition
EPA Severity Code: death, major, moderate, minor
Outcome: died, recovered, still treated, unknown

6. Along with the enhanced incident reporting, you must submit an analysis of all incidents seen, to include the following details:
 - a. All minor dermal and ocular irritation reports.
 - b. Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
 - c. A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
 - d. Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
 - e. A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
 - f. A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label.
 - g. A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range.
 - h. Table showing number of incidents for each dog breed.
 - i. Table showing number of incidents in dogs for each clinical sign.
 - j. Table showing number of incidents in dogs for each organ system.
 - k. Report aggregate incidents, but do not combine moderate and minor incidents.
7. If EPA determines that future mitigation measures are necessary for all pet spot-on products, the Agency will inform all registrants concerned. If mitigation measures are necessary, EPA may take regulatory action.
8. Hartz Mountain Corporation must adequately address all of the mitigation actions identified in the Agency's *Generic Pet Spot-On Mitigation Plan* available at the following internet site within 60 days following the date of this Notice of Registration: <http://www.epa.gov/pesticides/health/spot-on-meetings.html>.

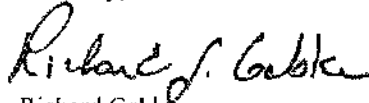
Page 5 of 5

You must submit and/or cite all data required for registration of your product under FIFRA Section 3(c)(5) when the Agency requires all registrants of similar products to submit such data, and submit acceptable responses required for registration review of your product under FIFRA.

Two copies of the finished labeling must be submitted prior to releasing the product for shipment. If you fail to comply with all of the **Terms of Registration** stated above, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e) and/or automatically expire. Your release for shipment of the product constitutes your acceptance of these conditions.

A copy of your label stamped "Accepted with Comments" is enclosed for your records. If you have any questions concerning this action, please contact me Richard J. Gebken at (703) 305-6701 or gebken.richard@epa.gov.

Sincerely,



Richard Gebken
Product Manager 10
Insecticide Branch
Registration Division (7305C)

Enclosure

Hartz® Reference # 130

Alternate Brand Names

Hartz® UltraGuard Plus® Flea (and) (&) Tick Topical Treatment for Dogs
Hartz® UltraGuard Pro® Flea (and) (&) Tick Topical Treatment for Dogs
Hartz® UltraGuard Max™ Flea (and) (&) Tick Topical Treatment for Dogs

Hartz® InControl Advanced® Flea (and) (&) Tick Topical Treatment for Dogs
Hartz® InControl Max™ Flea (and) (&) Tick Topical Treatment for Dogs

Revo Advanced™ Flea (and) (&) Tick Topical Treatment for Dogs

Hartz® Revo Advanced™ Flea (and) (&) Tick Topical Treatment for Dogs

Hartz® Pro Force™ Dual Action Topical Treatment for Dogs
Hartz® FieldForce™ Dual Action Topical Treatment for Dogs
Hartz® First Defense™ Dual Action Topical Treatment for Dogs

Hartz® Pro Force™ for Dogs
Hartz® FieldForce™ for Dogs
Hartz® First Defense™ for Dogs

ACCEPTED
With COMMENTS
In EPA Letter Dated:

JUL 9 2012
Under the Federal Insecticide, Fungicide
and Rodenticide Act, As amended, for the
pesticide Registered under EPA Reg. No:

2596-165

Hartz® UltraGuard Plus® Flea (and) (&) Tick Topical Solution for Dogs
Hartz® UltraGuard Pro® Flea (and) (&) Tick Topical Solution for Dogs
Hartz® UltraGuard Max™ Flea (and) (&) Tick Topical Solution for Dogs

Hartz® InControl Advanced® Flea (and) (&) Tick Topical Solution for Dogs
Hartz® InControl Max™ Flea (and) (&) Tick Topical Solution for Dogs

Revo Advanced™ Flea (and) (&) Tick Topical Solution for Dogs

Hartz® Revo Advanced™ Flea (and) (&) Tick Topical Solution for Dogs

Hartz® Pro Force™ Dual Action Topical Solution for Dogs
Hartz® FieldForce™ Dual Action Topical Solution for Dogs
Hartz® First Defense™ Dual Action Topical Solution for Dogs

Hartz® Pro Force™ for Dogs
Hartz® FieldForce™ for Dogs
Hartz® First Defense™ for Dogs

FieldForce™ Dual Action Topical Treatment for Dogs
First Defense™ Dual Action Topical Treatment for Dogs
FieldForce™ for Dogs
First Defense™ for Dogs

FieldForce™ Dual Action Topical Solution for Dogs
First Defense™ Dual Action Topical Solution for Dogs

[Each of the above brands will be packaged in the weight classes designated below:]

Weighing Up to 22 lbs.

Weighing 23 to 44 lbs.

Weighing 45 to 88 lbs.

Weighing 89 - 132 lbs.

ACTIVE INGREDIENTS:

Fipronil.....9.80%

(S)-Methoprene.....8.80%

OTHER INGREDIENTS 81.40%

TOTAL100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for additional precautionary statements.

NET CONTENTS: Contains *(number)* tubes, each fl. oz. (ml.)

For Dogs and Puppies Weighing:	Net Contents (Each tube)
Up to 22 lbs.	0.023 fl. oz. (0.67 ml.)
23 to 44 lbs.	0.045 fl. oz. (1.34 ml.)
45 - 88 lbs.	0.091 fl. oz. (2.68 ml.)
89 - 132 lbs.	0.136 fl. oz. (4.02 ml.)

EPA Reg. No. 2596-RAL

EPA Est. No.

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.

Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

[Cat Warning: A cat prohibition icon will appear on the front panel and back panels, and possibly an additional placement on a side panel.]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION.

~~Harmful if swallowed.~~ Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling.

HAZARDS TO DOMESTIC ANIMALS.

For external use only. Do not use on puppies under 8 weeks of age. ~~Individual sensitivities, while rare, may occur after using any pesticide product.~~ Pcts may experience some temporary irritation at the site of product application. ~~If signs persist, or become more severe within a few~~

~~days of application, consult a veterinarian immediately. If your pet has an unusual reaction to the initial application, consult a veterinarian before repeating treatment. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged animals.~~

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE: Do not use or store near heat or open flame.

FIRST AID

~~Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents, you may call 1-800-275-1414.~~

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment or advice.

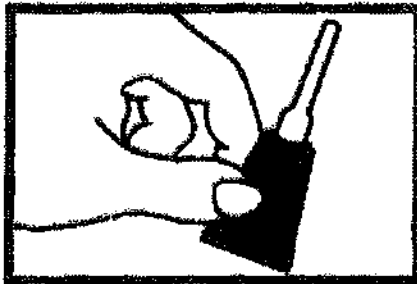
DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

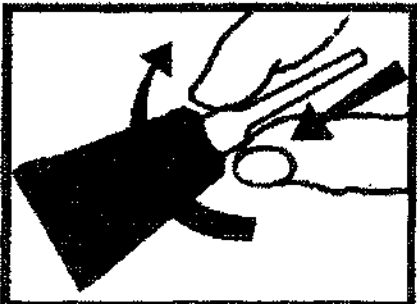
READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS OR ON PUPPIES 8 WEEKS OF AGE OR OLDER

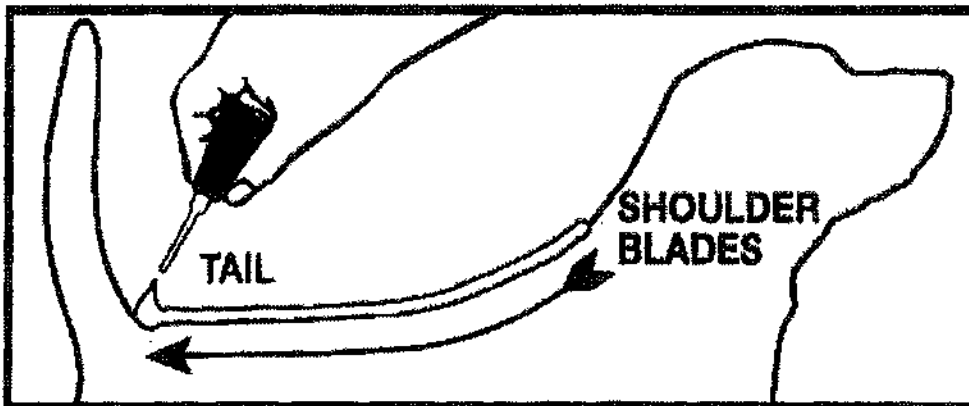
~~THIS PRODUCT IS APPROVED FOR USE ON ALL DOGS, INCLUDING BREEDING, PREGNANT AND LACTATING BITCHES~~



1 Remove one applicator tube from the package and hold in an upright position pointed away from your face.



2 Twist dispensing tip clockwise about $\frac{1}{2}$ turn while pushing down to break the tube's seal. Do not remove the dispensing tip.



3 Position the dispensing tip on the dog's back between the shoulder blades. Use the dispensing tip of the tube to part the dog's hair so that the product will be applied at skin level. Begin squeezing out the contents of the tube to form a stripe as you move from the shoulder blades along the dog's back to the base of the tail.

4 Repeat every month.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

PESTICIDE STORAGE: Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. *If empty:* Offer for recycling, if available. *If partly filled:* Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

For more information call our (flea and tick) experts at 1-800-275-1414 (weekdays, 9 am – 5 pm E.S.T.)

INDIVIDUAL TUBE TEXT

~~{Product name will be followed by weight of dog for which tube is intended}~~

~~{A duplicate weight class designation may be printed on the tube}~~

Active Ingredients:

Fipronil 9.8%, S-Methoprene 8.8%

Keep Out of Reach of Children

Caution

Read accompanying label before use

~~{Range of volumes from 0.023 fl. oz. (.67 ml) to 0.136 fl. oz. (4.02 ml) depending upon weight of dog}~~

EPA Reg. No. 2596-RAL

EPA Est. No.

OPTIONAL/ALTERNATE LABEL TEXT

~~Weighing up to 22lbs lbs.~~

~~Weighing 23 – 44 lbs.~~

~~Weighing 45 – 88 lbs.~~

~~Weighing 89 – 132 lbs.~~

[Adult Fleas]

Kills Fleas (that may transmit tapeworm) (for) (28 days) (30 days) (1 month) (4 weeks) ~~(on dogs)~~

Kills (Adult) Fleas (for up to 3 months)

Kills fleas that may cause (flea allergy dermatitis) (and) (flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) ~~(3 months)~~ (on dogs)

Kills newly emerged adult Fleas before they lay eggs

If there is a high risk for flea reinfestation, a once a month application may be needed

Stops existing infestations

Prevents establishment of new infestations

[Flea Eggs]

Kills Flea Eggs (and Flea Larvae) (for) (28 days) (30 days) (1 month) (4 weeks)

Prevents Flea Eggs from hatching

[Ticks]

Kills Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of) Brown Dog Ticks, American Dog Ticks, Lone Star Ticks and Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of) Deer Ticks (that may carry Lyme disease) (for) (28 days) (30 days) (1 month) (4 weeks) (on dogs)

Kills all biting stages of ticks

Kills adult (brown dog) (deer) ticks, nymphs and larvae

Kills Ticks including those that may transmit Lyme disease

[Lice & Mange]

Rapidly eliminates chewing lice infestations

Aids in Control of sarcoptic mange infestations

[Multiple]

Kills Fleas, Ticks, Flea eggs, Chewing Lice, (Flea larvae)

Kills Fleas, Ticks, Flea eggs, (Flea larvae) (through contact) (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, (Flea larvae), (Chewing lice) (through contact) (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, (Flea larvae) (after contact) (for) (28 days) (30 days) (1 month) (4 weeks)

Prevents development of all flea stages for up to 3 months.

Kills adult Fleas, Flea Eggs and Larvae ~~(for up to three months)~~

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, (Flea larvae) (after contact) (for) (28 days) (30 days) (1 month) (4 weeks)

Controls Flea and Tick infestations (on dogs) (for) (28 days) (30 days) (1 month) (4 weeks)

Provides fast, effective and convenient treatment and control of fleas, ticks, chewing lice and mosquitoes (for dogs and puppies)

Helps prevent re-infestation of fleas and ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Helps prevent flea and tick re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)

Kills flea eggs and flea larvae to help prevent future re-infestations
Kills all stages of the flea life cycle
Breaks the flea life cycle
Prevents all flea stages (eggs, larvae, pupae) from developing

[Mosquitoes]

Kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.
Kills Mosquitoes that may transmit West Nile virus (for) (28 days)(1 month) (4 weeks)(~~on dogs~~)
Kills Mosquitoes that may transmit heartworm (for) (28 days)(1 month) (4 weeks)(~~on dogs~~)

Controls flea and tick infestations

Once-a month Flea and Tick (Prevention) (Treatment) (Control) (Solution)
Monthly Flea and Tick (Prevention) (Treatment) (Control) (Solution)
(28 day) (30 day) (1 month) (4 week) Flea and Tick (Prevention) (Treatment) (Control) (Solution)
Prevents flea eggs from developing into biting adults (for) (up to) (30 days) (1 month) (4 weeks)
~~Gentle protection for dogs (and puppies)~~
~~Quick drying (formula)~~
~~Dries quickly~~
Stays on and doesn't rub off
~~Spreads with dog's natural skin oils~~
Kills fleas for 30 days (1 month) (4 weeks)
Stops and prevents infestations
Prevents re-infestation
Prevents and controls re-infestation(s)
Rapidly eliminates fleas
Fast acting
Long lasting
Effective and convenient topical treatment
Kills fleas (and ticks) through (after) contact
(With) patented applicator
(With) patent pending applicator
Waterproof
Easy spot on topical applicator

Do not reapply product for 30 days

Remains effective even after bathing, water immersion, or exposure to sunlight
(Product Name) remains effective even after bathing, water immersion, or exposure to sunlight.
Avoid contact with treated area until dry.
Can also be used on breeding, pregnant and lactating bitches
Convenient to use
Contains Fipronil and the insect growth regulator (IGR) (S)-Methoprene. (product name)
effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks and chewing lice.

New (Formula) ~~(claim to be removed after 6 months)~~

Contains Fipronil and (S)-Methoprene (, the active ingredients used in Frontline Plus®).
(Brand name) is not manufactured by or distributed by Merial. Frontline Plus® is a registered trademark of Merial.

Compare to Frontline Plus®

For dogs and puppies 8 weeks of age or older
~~Specially formulated for dogs and puppies~~

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

1st dose, 2nd dose, 3rd dose (Xth dose)

First month, second month, third month (Xth month)

Value pack

~~(X)~~ month supply

~~(X)~~ monthly treatment(s)

~~Fragrance-free~~

~~Unscented~~

Convenient (easy to use) applicator

X Pro-cision Flo® Applicator(s)

(Pro-cision Flo® Applicator)

Direct to your dog's skin

Easy (simple) to use (handle) (apply)

After application, the treated area may appear wet (or) (oily) for up to 24 hours

You may bathe your dog 48 hours after application

To help remind you when you last applied treatment, simply write in the date when each dose is applied:

First Dose _____

Second Dose _____

Third Dose _____

Xth Dose _____

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

DP BARCODE No.: 388640; **FILE SYMBOL No.:** 2596-RAA; **PRODUCT NAME:** Hartz Reference #131;
DECISION No.: 445037; **PC Code(s):** 129121, 105402; **ACTION CODE:** R-310; **FOOD Use:** No

DATE OUT: July 27, 2011

SUBJECT: End Use Product Chemistry Review
Product Name: Hartz Reference #131

FROM: Shyam Mathur
Product Chemistry Team Leader
Technical Review Branch/RD (7505P)

S. Mathur
7/27/11

TO: Bonaventure Akinlosotu / Richard Gebken, RM 10
Insecticide Branch / RD (7505P)

Company Name: The Hartz Mountain Corporation
Formulation Type: Insecticide

INTRODUCTION:

The registrant has submitted an application for the registration of the new end use product "Hartz Reference #131," a liquid flea and tick treatment combination product for cats and kittens containing Fipronil and (S)-Methoprene. In support of the registration application, the registrant has submitted 830 series group A product chemistry data with MRID Nos. 483790-03 and 483792-02, and 830 series group B data with MRID No. 483792-01. The registrant is using the "cite-all" method of support with Merial (EPA Co. No. 65331). The primary review on the product chemistry data was performed by Summitec Corporation, Knoxville, TN. TRB has been asked to determine the acceptability of the proposed basic CSF and the supporting product chemistry data.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient(s): Fipronil (9.80%) and (S)-Methoprene (11.80%)

2. Has the registrant claimed substantial similarity to a registered product?

☐ Yes; ☒ No; ☐ NA; if yes give the registration number of the cited product.

EPA Reg. No: NA

3. All of the source materials of the active ingredient are derived from registered sources- ☒ Yes ☐ No

4. All inert ingredients have been screened by IIAB and found to be approved for the proposed labeled uses.

DP BARCODE No.: 388640; FILE SYMBOL No.: 2596-RAA; PRODUCT NAME: Hartz Reference #131;
DECISION No.: 445037; PC Code(s): 129121, 105402; ACTION CODE: R-310; FOOD Use: No

5. Confidential Statement of Formula(s):

☒ Basic - Dated 2/4/2011; Re-submitted - Dated: NA

Alternate CSF(s) complies with 40CFR§152.43: ☐ Yes; ☐ No; ☒ NA

6. Product label

- a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concurs with product label (PR Notice 91-2).

☒ Yes; ☐ No; if not, explain below:

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredient)

☒ Yes; ☐ No; if not, explain below:

Metallic equivalent: ☐ Yes ☒ NA
Soluble arsenic: ☐ Yes ☒ NA
Isomeric ratios: ☐ Yes ☒ NA
Acid Equivalent: ☐ Yes ☒ NA; acid equivalent =

- b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: ☐ Yes ☒ No ☐ NA
Methanol at > 4%: ☐ Yes ☒ No ☐ NA
Sodium nitrate/Sodium nitrite: ☐ Yes ☒ No ☐ NA

- c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?

☒ Yes; ☐ No

(Combustible: Flashpoint = 40°C; 104°F)

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?

☐ Yes; ☐ No; ☒ NA; if not, explain below

- d. Label requires an additional Storage and Disposal statement:

☐ Yes; ☒ No; if yes explain below:

DP BARCODE No.: 388640; FILE SYMBOL No.: 2596-RAA; PRODUCT NAME: Hartz Reference #131;
 DECISION No.: 445037; PC Code(s): 129121, 105402; ACTION CODE: R-310; FOOD Use: No

7. Group A: Product Chemistry Data

TRB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		TRB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		X		A	483792-02 & CSF
830.1600	Description of materials used to produce the product		X		G	483792-02; MSDSs not provided
830.1650	Description of formulation process		X		A	483792-02
830.1670	Discussion on the formation of impurities		X		A	483792-02
830.1700	Preliminary analysis			X	NA	Not required
830.1750	Certified limits (158.350)	Standard certified limits	X		U	483792-02 & CSF; The lower limit for [REDACTED] (too high).
		Proposed Limits				
		Justification for wider limits				
830.1800	Enforcement analytical method		X		A	483790-03

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress, NA = Not Applicable; U = Upgradeable.

DP BARCODE No.: 388640; **FILE SYMBOL No.:** 2596-RAA; **PRODUCT NAME:** Hartz Reference #131;
DECISION No.: 445037; **PC Code(s):** 129121, 105402; **ACTION CODE:** R-310; **FOOD Use:** No

CONCLUSIONS:

The TRB has reviewed the product chemistry data submitted for the proposed end-use product and has concluded that:

1. The proposed CSF for the basic formulation of Hartz Reference #131 (dated 2/4/2011) is acceptable.
2. The product chemistry data submitted corresponding to guideline 830.1600 (description of materials used to produce the product) are not acceptable. The MSDSs for the starting materials were not provided.
3. The product chemistry data submitted corresponding to guideline 830.1650 (description of the formulation process) are acceptable.
4. The product chemistry data submitted corresponding to guideline 830.1670 (discussion of the formation of impurities) are acceptable.
5. The product chemistry data submitted corresponding to guideline 830.1750 (certified limits) are not acceptable [REDACTED] upper limit is too high.
6. The product chemistry data submitted corresponding to guidelines 830.6302 (color), 830.6303 (physical state), 830.6304 (odor), 830.7100 (viscosity), 830.614 (oxidation/reduction; chemical incompatibility), 830.6315 (flammability), 830.6316 (explosibility), 830.6321 (dielectric breakdown voltage), 830.7000 (pH), and 830.7300 (density) are acceptable. The registrant is using self-certification for the Group B data (EPA Form No. 8570-36).
7. Storage stability (830.6317) data and corrosion characteristics (830.6320) data for the product will be provided when the testing is complete. It is recommended that observations should be made at 0, 3, 6, 9, and 12 month intervals.
8. The proposed label was screened as it pertains to the product chemistry requirements. The final review of the proposed label and uses are the purview of the RM team.

DATA EVALUATION RECORD

FIPRONIL AND (S)-METHOPRENE (HARTZ REFERENCE #131)

STUDY TYPES: Product Identity and Composition (OPPTS 830.1550)
Description of Materials Used to Produce the Product (OPPTS 830.1600)
Description of the Formulation Process (OPPTS 830.1650)
Discussion of Formation of Impurities (OPPTS 830.1670)
Preliminary Analysis (OPPTS 830.1700)
Certified Limits (OPPTS 830.1750)
Enforcement Analytical Method (OPPTS 830.1800)
Physical and Chemical Characteristics (OPPTS 830.6302-830.7950)

MRIDs 483792-01, 483792-02, 483790-03

Prepared for
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by
Summitec Corporation
9724 Kingston Pike, Suite 602
Knoxville, Tennessee 37922

Task Order No. 3-A-65

Primary Reviewer:
Thomas C. Marshall, Ph.D.

Signature:
Date:

Thomas C. Marshall, Ph.D.
JUL 25 2011

Secondary Reviewers:
Eric Lewis, M.S.

Signature:
Date:

Eric B. Lewis
JUL 25 2011

Robert Ross, M.S., Program Manager

Signature:
Date:

Robert H. Ross
JUL 25 2011

Quality Assurance:
Angie Edmonds, B.S.

Signature:
Date:

Angie Edmonds
JUL 25 2011

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.
Summitec Corp. for the U.S. Environmental Protection Agency under Contract No. EP-W-11-014



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

August 5, 2011

MEMORANDUM

Subject: Name of Pesticide Product: HARTZ REFERENCE #131
EPA Reg. No. /File Symbol: 2596-RAA
DP Barcode: DP 388641
Decision No.: 445037
Action Code: R310
PC Codes: 129121 (Fipronil: 9.8%)
105402 (S-Methoprene: 11.8%)

From: Byron T. Backus, Ph.D., Toxicologist
Technical Review Branch
Registration Division (7505P)

Byron T. Backus
August 5, 2011

Washburn
T.L. Toxicology

To: Bonaventure Akinlosotu/Richard Gebken, RM 10
Insecticide Branch
Registration Division (7505P)

Registrant: THE HARTZ MOUNTAIN CORP.

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>by wt.</u>
129121 Fipronil	9.80%
105402 (S)-Methoprene	11.80%
<u>Other Ingredient(s):</u>	<u>78.40%</u>
TOTAL	100.00%

ACTION REQUESTED: The Risk Manager requests:

"For your review: An R310."

BACKGROUND:

The material received includes a Form 8570-1 (dated April 28, 2011) that states this product is similar in composition and labelling to EPA Reg. No. 65331-4 (Frontline Plus for Cats), a CSF dated February 4, 2011, a data matrix dated April 28, 2011 (which indicates the registrant is citing the following MRID studies to satisfy the acute toxicity data requirements: 43951703 [acute oral toxicity]; 44487701 [acute dermal toxicity]; 44433302 [acute inhalation toxicity]; 44942006 [primary eye irritation]; 45612702 [primary dermal irritation]; and 44942008 [dermal sensitization], and a proposed label (which, however, does not indicate the dosage rate or dosage rates for use on cats; the dosage rate for 65331-4 is 0.017 fl. oz. or 0.50 mL).

COMMENTS AND RECOMMENDATIONS:

1. After comparing the CSFs for 2596-RAA and EPA Reg. No. 65331-4, TRB concludes that the two formulations are toxicologically similar.
- ✓ 2. From OPPIN, the citation for MRID 43951703 is: *de Jouffrey, S. (1996) Acute Oral Toxicity in Rats: Frontline Top Spot (RM1601E/62): Lab Project Number: 13450 TAR. Unpublished study prepared by Centre International de Toxicologie. 49 p.* A check of IHAD gives no indication that this study has ever been reviewed. A cursory review of MRID 43951703 (from Documentrum) indicates the test material was RM1601E/62, containing 9.92% RM1601 (Fipronil). The rat oral LD₅₀ values with 95% confidence limits were: males: 2515 (1446-5020) mg/kg; females: 3259 (1869-8371) mg/kg. These are consistent with a Toxicity Category III classification by the oral exposure route.
3. From OPPIN, the citation for MRID 44487701 is: *Astruc, B.; Suberville, S.; Bosc, F. et al. (1998) Evaluation of the Presence of M&B 46513 on the Hair After a Topical Application (Spot-on or Spray) of Fipronil to the Dog: Final Report: Lab Project Number: MET419: R002459. Unpublished study prepared by Merial. 28 p.* This is not a dermal LD₅₀ study. According to our records, there is an acceptable rat dermal LD₅₀ study for this formulation (identified as RM1601E/62) in MRID 43577706 (review in TXR 5003209) with assignment to Toxicity Category IV by this exposure route.
- ✓ 4. From OPPIN, the citation for MRID 44433302 is: *Meo, N.; Gonzalez, C.; Mester, T. (1997) Dermal and Inhalation Exposure of Commercial Pet Groomers During Application of Frontline Spray Treatment: Final Report: Lab Project Number: MERIAL-445-SAFX1046: SAFX046: PDA9705. Unpublished study prepared by ABC Labs., California and Animal Appeal Grooming Shop & Case Veterinary Hospital. 1066 p.* This is not an inhalation LC₅₀ study. However, the Agency does not require inhalation LC₅₀ studies on pet spot-on products.
5. From OPPIN, the citation for MRID 44942006 is: *Findlay, J. (1999) Acute Eye Irritation Study of ML-2,095,988 508Q in Rabbits: Final Report: Lab Project Number: 1087SN4: PR&D 00295: PR&D 0029501. Unpublished study prepared by IIT Research Institute (IITRI). 18 p. {OPPTS 870.2400}.* The test material contained 10% fipronil and 12% S-methoprene. According to our records this study has been reviewed (TXR 5001486) and classified as acceptable. This citation can be used to satisfy the primary eye irritation study requirement for 2596-RAA. Although this study indicates a Toxicity Category IV classification by this exposure route, the label of the cited product (65331-4) includes the precautionary statement: "Causes eye irritation." and there is a first

aid statement for eye exposure, so 2596-RAA would be classified in Toxicity Category III by this exposure route.

6. From OPPIN, the citation for MRID 45612702 is: *Nolan-Smith, S. (2001) To Investigate the Safety of a Topical Formulation Containing ML-2,095,988 509T in Dogs Weighing Approximately 2kg (+/-1.5kg) at One, Three and Five Times the Maximum Label Recommended Dosage: Final Report: Lab Project Number: 1686/12: 1686/12-D2160: PR&D 0045801. Unpublished study prepared by Covance Laboratories. 324 p. {OPPTS 870.7200}*. This is not a primary dermal irritation study. According to our records, there is an acceptable primary dermal irritation study which can be used to satisfy this data requirement for 2596-RAA in MRID 44942007. This study was conducted on a formulation containing 10% fipronil and 12% S-methoprene (review in TXR 5001486) with assignment to Toxicity Category IV by this exposure route.
7. From OPPIN, the citation for MRID 44942008 is: *Findlay, J. (1999) Skin Sensitization Study of ML-2,095,988 508Q Using the Modified Buehler Method in Guinea Pigs: Final Report: Lab Project Number: 1087SN5: PR&D 00296: PR&D 0029601. Unpublished study prepared by IIT Research Institute (IITRI). 23 p. {OPPTS 870.2600}*. The test material contained 10% fipronil and 12% S-methoprene. According to our records this study has been reviewed (TXR 5001486) and classified as acceptable; the formulation is not a dermal sensitizer. This study can be used to satisfy the dermal sensitization study requirement for 2596-RAA.
8. TRB concludes that the registrant has given incorrect MRID citations for the dermal LD₅₀, inhalation LC₅₀, and primary dermal irritation studies in the data matrix dated April 28, 2011. These citations should be corrected before TRB makes precautionary and first aid labeling recommendations. The registrant should also provide the proposed dosage rate(s).
9. This review does not address the companion animal safety study requirements for 2596-RAA.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

August 9, 2011

MEMORANDUM

Subject: Name of Pesticide Product: HARTZ REFERENCE #131
EPA Reg. No. /File Symbol: 2596-RAA
DP Barcode: DP 388644
Decision No.: 445037
Action Code: R310
PC Codes: 129121 (Fipronil: 9.8%)
105402 (S-Methoprene: 11.8%)

From: Byron T. Backus, Ph.D., Toxicologist
Technical Review Branch
Registration Division (7505P)

Byron T. Backus
August 9 - 2011
M. Haslin

To: Bonaventure Akinlosotu/Richard Gebken, RM 10
Insecticide Branch
Registration Division (7505P)

Registrant: THE HARTZ MOUNTAIN CORP.

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>by wt.</u>
129121 Fipronil	9.80%
105402 (S)-Methoprene	11.80%
<u>Other Ingredient(s):</u>	<u>78.40%</u>
TOTAL	100.00%

ACTION REQUESTED: The Risk Manager requests:

"For your review: An R310."

BACKGROUND:

The material received includes a Form 8570-1 (dated April 28, 2011) that states this product is similar in composition and labelling to EPA Reg. No. 65331-4 (Frontline Plus for Cats), a CSF dated February 4, 2011, a data matrix dated April 28, 2011 (which indicates the registrant is citing the following MRIDs to satisfy the companion animal safety data requirements: 43863801 and 44942009), and a proposed label (which, however, does not indicate the dosage rate or dosage rates for use on cats; the dosage rate for 65331-4 is 0.017 fl. oz. or 0.50 mL).

COMMENTS AND RECOMMENDATIONS:

1. After comparing the CSFs for 2596-RAA and EPA Reg. No. 65331-4, TRB concludes that the two formulations are substantially similar in toxicity,
2. From OPPIN, the citation for MRID 43863801 is: *Cameron, D.; Maltby, B. (1995) Domestic Animal Safety by Topical Administration to Cats: Fipronil Spot Treatment: Lab Project Number: MRX 24/950746. Unpublished study prepared by Huntingdon Research Centre, Ltd. 174 p.*
3. From OPPIN, the citation for MRID 44942009 is: *Clery, D. (1999) Fipronil/(S)-Methoprene/Topical/Solution/Target Species Safety Study in the Cat: Interim Final Report: Lab Project Number: GB011/99-001: PR&D 0023301. Unpublished study prepared by Biological Labs. Europe Ltd. 137 p. {OPPTS 870.7200}.*
4. The studies in MRIDs 43863801 and 44942009 will support the use of this product on adult cats and kittens (\geq 8 weeks of age).
5. The proposed label for 2596-RAA includes the claim: "Can also be used on breeding, pregnant and lactating queens." In order to have this claim, the registrant has to cite the study in MRID 45618502: *Godin, C.; Alva, R. (2000) ML-2,095,988 508Q/Cat/Solution/Topical/Safety/Tolerance/Reproduction, Reactions: Final Report: Lab Project Number: PR&D 0020301: WEL 99886. Unpublished study prepared by White Eagle Toxicology Laboratory. 88 p.*
6. The proposed label for 2596-RAA includes the claim: "Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, chewing lice and mosquitoes." In order to have this claim, the registrant has to cite the study in MRID 43577716: *Villageliu, J.; Lopez, S.; Germa, M.; et al. (1994) Percutaneous Absorption and Distribution of Radioactivity in Hair, Skin, and Fat After Spot-On Application of (Carbon 14)-RM1601 in Cats: Lab Project Numbers: CD-93/3748F. Unpublished study prepared by Centro de Investigacion y Desarrollo Aplicado, S.A.L. 42 p.*
7. The registrant should also provide the proposed dosage rate(s) for 2596-RAA, which should be consistent with (no greater than) that of EPA Reg. No. 65331-4 (0.017 fluid oz. or 0.50 mL per application).

2596 - RAA



Recommendation of Division Directors Negotiated Due Dates has been completed by Marty Monell.

Workflow Messenger to: Marty Monell, Bonaventure Akinlosotu

08/31/2011 04:03 PM

Sent by: **Marty Monell**

Recommendation of Division Directors Negotiated Due Dates has been completed by Marty Monell.

Click on this link to access this form:

<https://webforms.epa.gov/webforms/webformsadmin.nsf/formOpen?OpenAgent&UNID=CEAD2D69E9099996852578F0005E0F85&USERDB=webforms/webformsapp.nsf>

Click on this link to access all your forms:

<https://webforms.epa.gov/webforms/webformsapp.nsf>

Recommendation of Division Directors Negotiated Due Dates			
Decision #:		Registration #:	
445034 445035		2596-RAG, RAU	
442436 & 445037		2596-RAL, RAA	
<input checked="" type="checkbox"/> See page 2 for additional registration entries			
Chemical Name: Fipronil, and Fipronil + S-Methoprene			
Fee Category: R310		PRIA Decision Time Frame: 6 Months	
Submitted by: Bonaventure Akinlosotu		Branch: DCSPP/OPP/RD	Date: 08/18/2011
Company: The Hartz Mountain Corp.			
Original PRIA Due Date: 09/08/2011		Proposed New PRIA Due Date: 03/08/2012	
Previous Negotiated Due Dates:			
Is the "Fix" in-house? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> n/a		If not, date "Fix" expected: 01/08/2012	
Negotiated Due Date Reason:			
Additional Data Required	<input type="checkbox"/> Product Chemistry <input type="checkbox"/> Efficacy	<input type="checkbox"/> Toxicology <input type="checkbox"/> Ecological	<input type="checkbox"/> Acute Tox <input type="checkbox"/> Residue <input checked="" type="checkbox"/> Other
Data Deficiencies	<input type="checkbox"/> Product Chemistry <input type="checkbox"/> Environmental	<input type="checkbox"/> Acute Tox <input type="checkbox"/> Ecological	<input type="checkbox"/> Efficacy <input type="checkbox"/> Labeling <input checked="" type="checkbox"/> Other <input checked="" type="checkbox"/> Not Submitted
Late Risk Assessment	<input type="checkbox"/> Human Health	<input type="checkbox"/> Ecological	
Interim Consideration	<input type="checkbox"/> Agency Initiated	<input checked="" type="checkbox"/> Registrant Initiated	
<input type="checkbox"/> CSF	<input type="checkbox"/> Public Process	<input type="checkbox"/> Risk Issues Environmental	<input type="checkbox"/> Risk Issues Human Health
<input type="checkbox"/> Impurities Review	<input type="checkbox"/> Label	<input type="checkbox"/> Administrative-FR Notice	<input checked="" type="checkbox"/> Other - Comment Field
Summary of Deficiency Type(s): <input checked="" type="checkbox"/> Not Submitted (N) <input checked="" type="checkbox"/> Deficiencies (D)			
Product Chemistry: <input type="checkbox"/> Acute Tox: <input type="checkbox"/> Efficacy: <input type="checkbox"/> Labeling: <input type="checkbox"/> Ecological Data: <input type="checkbox"/> Other (describe): <input checked="" type="checkbox"/>			
CRP data			
Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates): The product reviewer had several discussions with the registrant relative to the CRP requirement (See issues below).			
"75 Day" Letter sent? <input type="checkbox"/> Yes, Date sent <input checked="" type="checkbox"/> No and reason for none? Add comments on page 2			
Rationale for Proposed Due Date: Registrant plan to submit CRP data by 01/08/2011			
Registrant notified that this is the last negotiation? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> Not Applicable			
Approve: <input checked="" type="checkbox"/>		Disapprove: <input type="checkbox"/>	
If disapproved, action to be taken:			
OD or DOD Signature: CN=Marty Monell/OU=DC/O=USEPA/C=US		Date: 08/31/2011	

Decision #:	Registration #:	Petition #:
<p>Issue(s) (describe in detail):</p> <p>CRP is required for these products, and the registrant submitted a CRP testing protocol to the Agency for review. The protocol was acceptable with comments, and the Agency notified the registrant on 07/15/2011.</p> <p>After several phone conversations with the registrant to discuss options, the registrant agreed to a 6-month extension. This will allow the registrant to submit required CRP data, and for the Agency to complete the review of all data.</p> <p>The registrant was also notified that all deficiencies must be satisfactorily addressed by 01/08/2012 in order for the Agency to complete the registration process and issue a NOR by the renegotiated date.</p>		
<p>Comment(s):</p>		

Audit Trail for

Recommendation of Division Directors Negotiated Due Dates

PDF Name: PRIAv4a.pdf

Form Number: PRIA

Document Identifier: PRIA-11230130723-BA

SUBMITTED on 08/18/2011 at 02:10:54 PM by CN=Bonaventure Akintosoju/OU=DC/O=USEPA/C=US

APPROVED on 08/31/2011 at 03:27:38 PM by CN=Marion Johnson/OU=DC/O=USEPA/C=US

APPROVED on 08/31/2011 at 03:39:32 PM by CN=Lois Rossi/OU=DC/O=USEPA/C=US

APPROVED AND COMPLETED on 08/31/2011 at 04:03:34 PM by CN=Marty Monell/OU=DC/O=USEPA/C=US



THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094-3688 • 201/271-4800

August 10, 2011

Document Processing Desk
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: Mr. Richard Gebken (PM # 10)

**RE: HARTZ® Reference No. 128, File Symbol 2596-RAG
HARTZ® Reference No. 129, File Symbol 2596-RAU
HARTZ® Reference No. 130, File Symbol 2596-RAL
HARTZ® Reference No. 131, File Symbol 2596-RAA**

PRIA Code R340, Request for Extension of End Date

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094. would like to extend the PRIA conclusion date for these applications in order to provide the Agency sufficient time to review the Child Resistant Packaging data once it is submitted. Hartz is aware of the time requirements for Rosalind Gross to review the data and as a result, it is necessary to request this extension.

After several discussions with Bonaventure Akinlosotu, it was determined that The Hartz Mountain Company will request a 6-month extension, which will change the PRIA conclusion date for these applications from September 8, 2011 to March 8, 2012..

With this extension, Hartz will ensure that the necessary data is submitted in order for EPA to finalize the reviews. We understand that other reviews of our submission packages are well underway and we would like to keep the process moving forward.


If you have any questions or need additional information, please feel free to contact me at (201) 271-4800, ext. 7202 or <mailto:rosenwasser@hartz.com>.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert Rosenwasser". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Robert Rosenwasser
Director, Regulatory Affairs



Re: PRIA extension request 
Bonaventure Akinlosotu to: RRosenwasser
Cc: Richard Gebken, Marion Johnson

2596- RAG
RAU
RAL
RAA

08/11/2011 10:27 AM

This is to acknowledge receipt of your "Request for Extension of PRIA Due Date", which is being used to initiate the approval process. You will be kept abreast of further actions.

Thanks,

B.A

RRosenwasser

Bonaventure: As discussed, please find attache...

08/10/2011 09:11:40 AM

From: RRosenwasser@hartz.com
To: Bonaventure Akinlosotu/DC/USEPA/US@EPA
Cc: Richard Gebken/DC/USEPA/US@EPA
Date: 08/10/2011 09:11 AM
Subject: PRIA extension request

Bonaventure:

As discussed, please find attached letter. A formal copy is being submitted through the Front End Desk.
Robert

See copy
of renegotiated

Robert Rosenwasser
Director, Regulatory Affairs
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094-3688
email: rosenwasser@hartz.com
phone: 201-271-4800, ext. 7202 [attachment "Hartz PRIA extension.pdf" deleted by Bonaventure Akinlosotu/DC/USEPA/US]

Hartz® Reference # 131

Alternate Brand Names

Hartz® UltraGuard Plus® Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)
Hartz® UltraGuard Pro® Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)
Hartz® UltraGuard Max™ Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)

Hartz® InControl Advanced® Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)
Hartz® InControl Max™ Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)

Revo™ Advanced™ Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)

Hartz® Revo Advanced™ Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)

Hartz® Pro Force™ Dual Action Topical Treatment for Cats (& Kittens)
Hartz® FieldForce™ Dual Action Topical Treatment for Cats (& Kittens)
Hartz® First Defense™ Dual Action Topical Treatment for Cats (& Kittens)

Hartz® Pro Force™ for Cats (& Kittens)
Hartz® FieldForce™ for Cats (& Kittens)
Hartz® First Defense™ for Cats (& Kittens)
Hartz® UltraGuard Plus® Flea (and) (&) Tick Topical Solution for Cats (& Kittens)
Hartz® UltraGuard Pro® Flea (and) (&) Tick Topical Solution for Cats (& Kittens)
Hartz® UltraGuard Max™ Flea (and) (&) Tick Topical Solution for Cats (& Kittens)
Hartz® InControl Advanced® Flea (and) (&) Tick Topical Solution for Cats (& Kittens)
Hartz® InControl Max™ Flea (and) (&) Tick Topical Solution for Cats (& Kittens)
Revo Advanced™ Flea (and) (&) Tick Topical Solution for Cats (& Kittens)
Hartz® Revo Advanced™ Flea (and) (&) Tick Topical Solution for Cats (& Kittens)
Hartz® Pro Force™ Dual Action Topical Solution for Cats (& Kittens)
Hartz® FieldForce™ Dual Action Topical Solution for Cats (& Kittens)
Hartz® First Defense™ Dual Action Topical Solution for Cats (& Kittens)
FieldForce™ Dual Action Topical Treatment for Cats (& Kittens)
First Defense™ Dual Action Topical Treatment for Cats (& Kittens)
FieldForce™ for Cats (& Kittens)
First Defense™ for Cats (& Kittens)
FieldForce™ Dual Action Topical Solution for Cats (& Kittens)
First Defense™ Dual Action Topical Solution for Cats (& Kittens)

ACTIVE INGREDIENTS:

Fipronil.....	9.80%
(S)-Methoprene.....	11.80%
OTHER INGREDIENTS	78.40%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for additional precautionary statements.

NET CONTENTS: Contains (*number*) tubes, each __ fl. oz. (__ ml)

EPA Reg. No. 2596-RAA
EPA Est. No.

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.
Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION.

Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling.

HAZARDS TO DOMESTIC ANIMALS.

For external use only. Do not use on kittens under 8 weeks of age. Individual sensitivities, while rare, may occur after using any pesticide product. Pets may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian immediately. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged animals. Call 1-800-275-1414 for 24-hour assistance.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE: Do not use or store near heat or open flame.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents, you may call 1-800-275-1414.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Flush eyes with plenty of water. Call a doctor if irritation persists.

IF ON SKIN OR CLOTHING: Wash with plenty of soap and water. Get medical attention if irritation persists.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR PET READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.

To kill fleas, all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks [which may carry Lyme disease], chewing lice and mosquitoes, apply to cats and kittens [8 weeks or older] as follows:

[USE DIRECTIONS HERE]

(The application steps below may optionally be numbered or bulleted to clarify the order, depending on the final physical layout of the label)

[Option 1 capped tube]

Remove one applicator tube from the package and hold in an upright position (pointed away from your face). Pull off cap. Turn the cap around and place on top of tube. Simply press cap down to break the seal of the tube. Remove cap carefully. Position the tip of the tube on the cat's back between the shoulder blades. Use the tip of the tube to part the cat's hair so that the product will be applied at skin level. (Do not bathe your cat 48 hours prior to application.) Squeeze applicator, applying entire contents in a single spot on the animal's skin. Separate treated cat from other (dogs and cats) (pets) for 24 hours after treatment has been applied. Repeat every month.

[Option 2 applicator tube]

Remove one applicator tube from the package and hold in an upright position pointed away from your face. Twist dispensing tip clockwise about ½ turn while pushing down to break the tube's seal. Do not remove the dispensing tip. Position the dispensing tip on the cat's back between the shoulder blades. Use the dispensing tip of the tube to part the cat's hair so that the product will be applied at skin level. (Do not bathe your cat 48 hours prior to application.) Squeeze applicator, applying entire contents in a single spot on the animal's skin. Separate treated cat from other (dogs and cats) (pets) for 24 hours after treatment has been applied. Repeat every month.

PRODUCT NAME contains Fipronil and the insect growth regulatory (IGR) (S)-Methoprene. PRODUCT NAME effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, chewing lice and mosquitoes.

PRODUCT NAME can also be used for the treatment and control of mosquitoes, and flea, tick and chewing lice infestations on breeding, pregnant and lactating queens.

FREQUENCY OF APPLICATION

When used monthly, PRODUCT NAME completely breaks the flea life cycle and controls tick and chewing lice infestations. Research demonstrates that PRODUCT NAME kills adult fleas, flea eggs, and flea larvae for up to six weeks. PRODUCT NAME also prevents development of all flea stages for up to six weeks. PRODUCT NAME kills ticks for a least one month. A once monthly application is recommended where tick control is needed. Although PRODUCT NAME can control fleas for up to six weeks, if there is a high risk of reinfestation or if the pet has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

With a monthly application of PRODUCT NAME kills mosquitoes within 24 hours for up to 14 days and within 48 hours for up to 28 days.

PRODUCT NAME remains effective even after bathing, water immersion, or exposure to sunlight. Avoid contact with treated area until dry. Do not reapply PRODUCT NAME for 30 days.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

STORAGE. Store unused product in original container, out of reach of children and animals.

PESTICIDE DISPOSAL. If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

CONTAINER DISPOSAL. If empty: Do not reuse this container. Place in trash or offer for recycling if available.

For more information call our (flea and tick) experts at 1-800-275-1414 (weekdays, 9 am – 5 pm E.S.T.)

INDIVIDUAL TUBE TEXT

Product Name

Active Ingredients:

Fipronil 9.8%, (S)-Methoprene 11.8%

Keep Out of Reach of Children

Caution

Read accompanying label before use

EPA Reg. No. 2596-RAA

EPA Est. No.

Product Name can also be used for the treatment and control of mosquitoes, and flea, tick and chewing lice infestations on breeding, pregnant and lactating queens.

Product Name contains Fipronil and the insect growth regulator (IGR) (S)-Methoprene. Product Name effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, chewing lice and mosquitoes.

Stops and prevents infestations

Kills adult fleas, flea eggs, and flea larvae

Prevents all flea stages (eggs, larvae, pupae) from developing

Kills fleas which may cause flea allergy dermatitis

Kills all stages of Deer Ticks (which may carry Lyme disease), Brown Dog Ticks, American Dog Ticks, and Lone Star Ticks

Kills mosquitoes

Prevents and controls reinfestations

Rapidly eliminates infestations with chewing lice

Can also be used on breeding, pregnant and lactating queens

Fast-acting

Long-lasting

Waterproof

Convenient to use

[Adult Fleas]

Kills Fleas (that may transmit tapeworms) (for) (28 days) (30 days) (1 month) (4 weeks) (on cats)

Kills (Adult) Fleas (for up to 3 months)

Kills fleas that may cause (flea allergy dermatitis) (and) (flea bite anemia) (for) (28 days) (30 days) (1 month) (4 weeks) (3 months) (on cats)

Kills newly emerged adult Fleas before they lay eggs

If there is a high risk for flea reinfestation, a once a month application may be needed

Stops existing infestations
Prevents establishment of new infestations

[Flea Eggs]

Kills Flea Eggs (and Flea Larvae) (for) (28 days) (30 days) (1 month) (4 weeks)
Prevents Flea Eggs from hatching

[Ticks]

Kills Ticks (for) (28 days) (30 days) (1 month) (4 weeks)
Kills (all stages of) Brown Dog Ticks, American Dog Ticks, Lone Star Ticks and Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)
Kills (all stages of) Deer Ticks (that may carry Lyme disease) (for) (28 days) (30 days) (1 month) (4 weeks) (on cats)
Kills all biting stages of ticks
Kills adult (brown dog) (deer) ticks, nymphs and larvae
Kills Ticks including those that may transmit Lyme disease

[Lice & Mange]

Rapidly eliminates chewing lice infestations
Aids in Control of sarcoptic mange infestations

[Multiple]

Kills Fleas, Ticks, Flea eggs, Chewing Lice, (Flea larvae)
Kills Fleas, Ticks, Flea eggs, (Flea larvae) (through contact) (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea Eggs, (Flea larvae), (Chewing lice) (through contact) (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea eggs, (Flea larvae) (after contact) (for) (28 days) (30 days) (1 month) (4 weeks)
Prevents development of all flea stages for up to 3 months.
Kills adult Fleas, Flea Eggs and Larvae (for up to three months)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, (Flea larvae) (after contact) (for) (28 days) (30 days) (1 month) (4 weeks)
Controls Flea and Tick infestations (on cats) (for) (28 days) (30 days) (1 month) (4 weeks)
Provides fast, effective and convenient treatment and control of fleas, ticks, chewing lice and mosquitoes (for cats and kittens)

Helps prevent re-infestation of fleas and ticks (for) (28 days) (30 days) (1 month) (4 weeks)
Helps prevent flea and tick re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)
Kills flea eggs and flea larvae to help prevent future re-infestations
Kills all stages of the flea life cycle
Breaks the flea life cycle
Prevents all flea stages (eggs, larvae, pupae) from developing

[Mosquitoes]

Kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.

Kills Mosquitoes that may transmit West Nile virus (for) (28 days)(1 month) (4 weeks)(on cats)

Kills Mosquitoes that may transmit heartworm (for) (28 days)(1 month) (4 weeks)(on cats)

Controls flea and tick infestations

Once-a month Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Monthly Flea and Tick (Prevention) (Treatment) (Control) (Solution)

(28 day) (30 day) (1 month) (4 week) Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Prevents flea eggs from developing into biting adults (for) (up to) (30 days) (1 month) (4 weeks)

Gentle protection for cats (and kittens)

Quick drying (formula)

Dries quickly

Stays on and doesn't rub off

Spreads with cat's natural skin oils

Kills fleas for 30 days (1 month) (4 weeks)

Stops and prevents infestations

Prevents re-infestation

Prevents and controls re-infestation(s)

Rapidly eliminates fleas

Fast acting

Long lasting

Effective and convenient topical treatment

Kills fleas (and ticks) through (after) contact

(With) patented applicator

(With) patent pending applicator

Waterproof

Easy spot on topical applicator

Do not reapply product for 30 days

Remains effective even after bathing, water immersion, or exposure to sunlight

(Product Name) remains effective even after bathing, water immersion, or exposure to sunlight.

Avoid contact with treated area until dry.

Can also be used on breeding, pregnant and lactating queens

Convenient to use

Contains Fipronil and the insect growth regulator (IGR) (S)-Methoprene. (product name)

effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks and chewing lice.

New (Formula) (*claim to be removed after 6 months*)

Contains Fipronil and (S)-Methoprene (, the active ingredients used in Frontline Plus®).

(Brand name) is not manufactured by or distributed by Merial. Frontline Plus® is a registered trademark of Merial.

Compare to Frontline Plus®

For cats and kittens 8 weeks of age or older
Specially formulated for cats and kittens

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

1st dose, 2nd dose, 3rd dose (Xth dose)

First month, second month, third month (Xth month)

X-pack

X-tubes

Value pack

X month supply

X monthly treatment(s)

Fragrance-free

Unscented

Fresh (scent) (fragrance)

Powder (scent) (fragrance)

Pleasant (scent) (fragrance)

Spring Fresh Scent

Convenient (easy to use) applicator

X Pro-cision Flo® Applicator(s)

With Pro-cision Flo® Applicator

Featuring Pro-cision Flo® Applicator (for easy application)

Direct to your cat's skin

Easy (simple) to use (handle) (apply)

(Featuring the) (with) EZC™ tube

(Featuring the) (with) EZ2C™ tube

(Featuring the) (with) EZView™ tube

(Featuring the) (with) EZView™ tube

(Featuring the) (with) Clearview™ tube

(Featuring the) (with) Clearview™ tube

(Clearview™) (EZC™) (EZ2C™) (EZView™) tube (visually) ensures all product has been dispensed

(Clearview™) (EZC™) (EZ2C™) (EZView™) tubes give you the assurance all the product has been applied

After application, the treated area may appear wet (or) (oily) for up to 24 hours

You may bathe your cat 48 hours after application

To help remind you when you last applied treatment, simply write in the date when each dose is applied:

First Dose _____

Second Dose _____

Third Dose _____
Xth Dose _____

Hartz[®] and other trademarks are trademarks of The Hartz Mountain Corporation



Completed Protocol Review: 2596-RAG, etc.
Bonaventure Akinlosotu to: RRosenwasser
Cc: Richard Gebken, Marion Johnson

07/15/2011 12:22 PM

Mr. Rosenwasser:

Please see attached docs (Cover letter and reviews) relative to the subject action.



[Untitled].pdf



[Untitled].pdf



[Untitled].pdf

Thanks,
B.A.

Bonaventure Akinlosotu, PhD
U.S. Environmental Protection Agency
Office of Chemical Safety and Pollution Prevention
OPP/RD (Mail Code: 7505P)
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Physical Address
One Potomac Yard
2777 Crystal Dr.
Arlington, VA 22202

703-605-0653
akinlosotu.bonaventure@epa.gov

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

July 15, 2011

Robert Rosenwasser, Director
Regulatory Affairs
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094

Subject: Testing Protocol for Child Resistant Packaging (CRP)
for four (4) Spot-On Fipronil-Containing Products

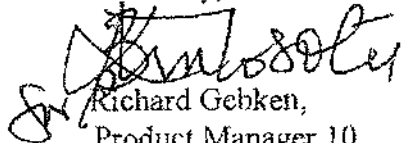
Hartz Reference No. 128: EPA File Symbol 2596-RAG
Hartz Reference No. 129: EPA File Symbol 2596-RAU
Hartz Reference No. 130: EPA File Symbol 2596-RAL
Hartz Reference No. 131: EPA File Symbol 2596-RAA

Submissions dated March 17 and April 28, 2011

Dear Mr. Rosenwasser:

The above referenced protocol submitted for review by the Agency has been evaluated, and found to be acceptable with the changes provided. Some issues need to be addressed as indicated in the accompanying Agency's "CRP reviews" dated June 2 & 14, 2011. If you have any questions concerning this action please contact Dr. B.A. Akinlosotu at (703) 605-0653.

Sincerely,


Richard Gebken,
Product Manager 10

Insecticide Branch
Registration Division (7505P)

NIB: See 2596-RAG for
copies of reviews



Enclosure Docs: Agency's "CRP Reviews"



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May 3, 2011

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

THE HARTZ MOUNTAIN CORP.
ATTN: ROBERT ROSENWASSER
400 PLAZA DRIVE
SECAUCUS, NJ 07094-

PRODUCT NAME: HARTZ REFERENCE #131
COMPANY NAME: THE HARTZ MOUNTAIN CORP.
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 2596-RAA
EPA RECEIPT DATE: 05/02/11

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 10, at (703) 305-6701.

Sincerely,

A handwritten signature in cursive script, appearing to read "J. E. Moore".

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division



THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094 201/271-4800
REGULATORY AFFAIRS

April 28, 2011

Document Processing Desk
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: **Mr. Richard Gebken (PM # 10)**

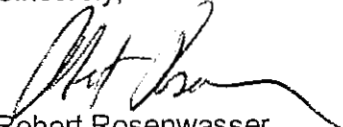
RE: Agency letter dated March 16, 2011
HARTZ® Reference No. 128, File Symbol 2596-RAG
HARTZ® Reference No. 129, File Symbol 2596-RAU
HARTZ® Reference No. 130, File Symbol 2596-RAL
HARTZ® Reference No. 131, File Symbol 2596-RAA

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688 is submitting the requested information to satisfy the deficiencies in our registration applications as noted in the Agency letter dated March 16, 2011:

1. New data matrices are submitted for each registration demonstrating the data citations being used for the proposed claims. Public versions are also enclosed. Because Hartz is relying on the selective method of support, new Certifications with Respect to Citation of Data are also submitted.
2. Revised application forms (8570-1) for each are included that demonstrates which of our proposed products is similar in composition and labeling to the related Frontline product.
3. Regarding Child Resistant Packaging (CRP), we are including the Receipt of Protocol Subject to Registration Service Fee (PRIA Code 272) dated March 21, 2011 (MRID 48424401). Any data that demonstrates that fipronil is a neurotoxin above the level of 28.5 mg that may be found in any proposed dose volume (requiring CRP) is information that would be found in the generic database of the technical active and would be captured from the filed Formulator's Exemption for each product. No individual MRID for this information is contained in the supplied Data Matrices.
4. Although not a noted deficiency, Hartz is submitting new CSF's for each product to show the inclusion of [REDACTED].

If you have any questions or need additional information, please feel free to contact me at (201) 271-4800, ext. 7202 or <mailto:rrosenwasser@hartz.com>.

Sincerely,


Robert Rosenwasser
Director, Regulatory Affairs

Inert ingredient information may be entitled to confidential treatment



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 2596-RAA	2. EPA Product Manager R. Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) HARTZ Reference # 131	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) The Hartz Mountain Corporation 400 Plaza Drive Secaucus, NJ 07094-3688 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 65331-4 Product Name Frontline Plus for Cats	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

New product registration.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt. 0.50 mL	No. per container 1-150	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 0.50 mL (multiple tubes per package)		5. Location of Label Directions <input checked="" type="checkbox"/> on outer packaging	
6. Manner in Which Label is Affixed to Product label is printed on packaging		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input checked="" type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other inner dosage tubes have required text printed on them	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Robert Rosenwasser		Title Director, Regulatory Affairs		Telephone No. (Include Area Code) 201-271-4800, ext. 7202	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Director, Regulatory Affairs			
4. Typed Name Robert Rosenwasser		5. Date April 28, 2011			



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094, 201-271-4800	EPA Registration Number/File Symbol 2595-RAA
Active Ingredient(s) and/or representative test compound(s) Fipronil, (S)-methoprene	Date April 28, 2011
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor Residential	Product Name Hartz Reference #131

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Date

April 28, 2011

Typed or Printed Name and Title


Robert Rosenwasser, Director, Regulatory Affairs



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

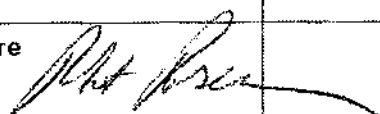
Date April 28, 2011			EPA Reg. No./File Symbol 2596-RAA		Page 1 of 2
Applicant's/Registrant's Name & Address: Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094			Product Hartz Reference #131		
Ingredient Fipronil(S)-Methoprene					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830-1550	Product identification and composition	submitted	Hartz	Own	
830-1600	Beginning materials	submitted	Hartz	Own	
830-1650	Description of formulation process	submitted	Hartz	Own	
830-1670	Formation of impurities	submitted	Hartz	Own	
830-1750	Certified limits	submitted	Hartz	Own	
830-1800	Enforcement analytical method	submitted	Hartz	Own	
830-6302	Color	submitted	Hartz	Own	Self-certification
830-6303	Physical state	submitted	Hartz	Own	
830-6304	Odor	submitted	Hartz	Own	Self-certification
830-6314	Oxidation/Reduction	Waiver	Hartz	Own	Self-certification
830-6315	Flammability	submitted	Hartz	Own	Self-certification
830-6316	Explosibility	Waiver	End use product is not potentially explosive.		
830-6317	Storage stability	To be submitted	Hartz	Own	In progress
Signature 			Name and Title Robert Rosenwasser Director, Regulatory Affairs		Date April 28, 2011



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date			EPA Reg. No./File Symbol 2596-RAA		Page 2 of 2
Applicant's/Registrant's Name & Address : Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094			Product Hartz Reference #131		
Ingredient Fipronil(S)-Methoprene					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830-6320	Corrosion characteristics	To be submitted	Hartz	Own	In progress
830-6321	Dielectric breakdown voltage	Waiver	End use product is not to be used around electrical equipment.		
830-7000	pH	Waiver	End use product is not to be dispersed with water.		
830-7100	Viscosity	submitted	Hartz	Own	Self-certification
870-1100	Acute oral toxicity	43951703	Merial		
870-1200	Acute dermal toxicity	44487701	Merial		
870-2400	Acute eye irritation	44433302	Meria		
870-1300	Acute inhalation toxicity	44942006	Merial		
870-2500	Acute dermal irritation	45612702	Merial		
870-2600	Skin sensitization	44942008	Merial		
810-3300	Product performance, efficacy	45618501, 45628101, 45628102, 45628103, 45628104, 46019201, 46019202	Merial		
870-7200	Domestic Animal Safety	43863801, 44942009	Merial		
Signature 			Name and Title Robert Rosenwasser Director, Regulatory Affairs		Date April 28, 2011 147


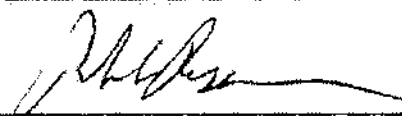


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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WASHINGTON, D.C. 20460

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DATA MATRIX

Date April 28, 2011		EPA Reg. No./File Symbol 2596-RAA		Page 1 of 2	
Applicant's/Registrant's Name & Address: Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094		Product Hartz Reference #131			
Ingredient Fipronil/(S)-Methoprene					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Hartz	Own	
			Hartz	Own	
			Hartz	Own	
			Hartz	Own	
			Hartz	Own	
			Hartz	Own	
			Hartz	Own	Self-certification
			Hartz	Own	
			Hartz	Own	Self-certification
			Hartz	Own	Self-certification
			Hartz	Own	Self-certification
			Hartz	Own	in progress
Signature 		Name and Title Robert Rosenwasser Director, Regulatory Affairs		Date April 28, 2011	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director: OPPE Information Management Division (2137) U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date	EPA Reg. No./File Symbol 2596-RAA	Page 2 of 2			
Applicant's/Registrant's Name & Address : Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094		Product Hartz Reference #131			
Ingredient Fipronil(S)-Methoprene					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Hartz	Own	In progress
			End use product is not to be used around electrical equipment.		
			End use product is not to be dispersed with water.		
			Hartz	Own	Self-certification
			Merial		
			Merial		
			Merial		
			Merial		
			Merial		
			Merial		
Signature			Name and Title Robert Rosenwasser Director, Regulatory Affairs		Date April 28, 2011

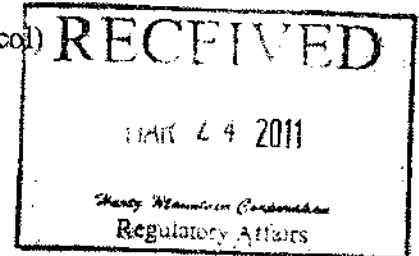


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 21, 2011

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-446735
EPA File Symbol or Registration Number: 2596-RAG (CRP testing protocol)
Product Name: HARTZ REFERENCE #128
EPA Receipt Date: 18-Mar-2011
EPA Company Number: 2596
Company Name: THE HARTZ MOUNTAIN CORP.



THE HARTZ MOUNTAIN CORP.
ATTN: ROBERT ROSENWASSER
400 PLAZA DRIVE
SECAUCUS, NJ 07094-

SUBJECT: Receipt of Protocol Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your protocol and certification of payment. If you submitted data with this action, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R272

APPLICANT-INITIATED 2;EXCLUDES DART, PRE-REGISTRATION CONFERENCES,
RAPID RESPONSE REVIEW, DNT PROTOCOL REVIEW, PROTOCOLS NEEDING HSRB
REVIEW;REVIEW OF STUDY PROTOCOL;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee
Ombudsman at (703) 308-9362.

Sincerely, *Teresa Downs*
Front End Processing Staff
Information Technology & Resources Management Division



THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094 201/271-4800
REGULATORY AFFAIRS

March 17, 2011

Document Processing Desk
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: Mr. Richard Gebken (PM # 10)
Hartz Reference #128, EPA File Symbol 2596-RAG
Hartz Reference #129, EPA File Symbol 2596-RAU
Hartz Reference #130, EPA File Symbol 2596-RAL
Hartz Reference #131, EPA File Symbol 2596-RAA

**Protocol submission and review for Child Resistant Packaging for
Products containing Fipronil – PRIA action code R272**

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688 is submitting a protocol for testing of packaging to determine whether packages of end-use products containing the active ingredient, Fipronil, are child resistant.

The testing that will take place after the protocol is approved by EPA will support the registration applications of the 4 products listed above.

The Hartz Mountain Corporation is submitting the following:

- Hartz Test #2278, Hartz UltraGuard Flea and Tick Topical Treatment, Child-resistant Package Test Protocol, Prepared by National Child Resistant Testing, Inc., Lincoln, NE – 3 copies
- PRIA fee paid by check for \$2,294.00

If you have any questions or need additional information, please feel free to contact me at (201) 271-4800, ext. 7202 or <mailto:rosenwasser@hartz.com>.

Sincerely,

Robert Rosenwasser
Director, Regulatory Affairs

48424401



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

March 16, 2011

Certified Mail: (Article Number 7005-3110-0001-4053-8914)

OPP Decision Numbers: 445034, 445035, 445036 & 445037

Registrant Name: The Hartz Mountain Corp.
(Attn: Robert Rosenwasser, Director, Regulatory Affairs)

Registrant Address: 400 Plaza Drive, Secaucus, NJ 07094

Subject: Data and Labeling Deficiencies

Product Name (EPA File Symbol)

Hartz Ref #s 128 (File Symbol 2596-RAG)

Hartz Ref #s 129 (File Symbol 2596-RAU)

Hartz Ref #s 130 (File Symbol 2596-RAL)

Hartz Ref #s 131 (File Symbol 2596-RAA)

Date of Applications: February 4, 2011

EPA Receipt Date: February 8, 2011

Dear Mr. Rosenwasser:

The Agency has received and begun its in-depth review of each subject applications, and has determined that it is incomplete and that further information is needed. This letter is a written notification of those deficiencies and identifies your options under 40 CFR 152.105 and Section 33 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), also known as the Pesticide Registration Improvement Renewal Act (PRIA 2). Your options under 40 CFR 152.105 and section 33 of FIFRA are addressed separately because each involves a different timeframe and set of options for responding to this letter. Please ensure that you consider each of the sections below in determining how and when you respond to this letter.

40 CFR 152.105:

Pursuant to 40 CFR 152.105, you are allowed 75 days from the date of this letter ending **May 31, 2011** to provide a response concerning the deficiencies listed in this letter. Your response may include making corrections or additions to complete the applications, or notifying the Agency of the date on which you expect to complete the applications, or withdrawing your applications. If you do not respond to this letter within 75 days or if you respond with a date on which you expect to complete the applications but fail to meet that scheduled date, the Agency will treat the applications as if you had withdrawn it. Withdrawal concludes the Agency's review of your applications. Any subsequent submission of the same application must then be submitted as a new application with a new deadline for EPA to make a determination on your application and subject to a new registration service fee.

The deficiencies identified in the Agency's review at this time are as follows:

1. The data matrix for each of the above referenced proposed products is incomplete. You must revise each data matrix accordingly. Instructions for completing the EPA form 8570-35 data matrix correctly can be found within PR Notice 98-5. An electronic copy of this PR Notice can be obtained at the following Agency web site:
http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
 - The data matrix (if using Cite All) must include all companies listed on the data submitters list for each active ingredient. Documentation that offers to pay must be available to the Agency on request. Refer to Section III of the 8570-34 form for specifics.
2. As required on the Application Form (8570-1), no me-too product was listed for each proposed product. Per your request for a PRIA Code R310, you must provide information on the specific product(s) to which each proposed product is similar or identical in composition and labeling.
3. The aforementioned pending applications contain no information on Child Resistant Packaging (CRP) and Companion Animal Safety data.
 - You must provide appropriate information to adequately address CRP and Companion Animal Safety requirements.
 - Child Resistant Packaging is unique for each product, and cannot be cited.
 - The Agency does not accept CRP Self Certification for pending registrations requiring data.

Further review of your applications and your response to the aforementioned deficiencies may reveal additional deficiencies, and you will be so informed.

FIFRA Section 33/PRIA:

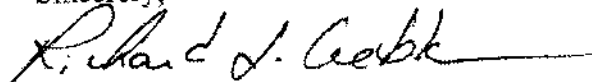
These applications is also subject to a deadline for making a determination on the applications under FIFRA Section 33, Pesticide Registration Service Fees, established under PRIA.

The time frame for the Agency to make a determination on each of these applications ends on September 08, 2011; and you have the following three options:

1. **Correct application deficiencies:** All required additional information must adequately address the stated deficiencies, and must be received by the Agency on or before **May 30, 2011**. The Agency will not proceed with the processing of these applications until all the deficiencies are adequately corrected. When all of the required information including acceptable data is received on or before May 31, 2011 by the Agency, you will be notified of the need for additional time and or resources needed to adequately review and process your applications.
2. **Withdraw the applications:** You may notify the Agency before May 31, 2011 that you are withdrawing your applications. As noted above, withdrawal concludes the Agency's review of your applications; however, you may resubmit your applications after the deficiencies have been addressed. Should you choose to resubmit your applications, it would be subject to a new deadline for making a determination on your applications and a new registration service fee. Since a fee was paid with these applications, the Agency will provide any applicable refund as soon as practicable.
3. **Not respond:** If you do not respond or fail to provide the Agency with the above stated information on or before **May 31, 2011**, the Agency will administratively withdraw your applications.

Please respond to this letter by contacting me (Phone: 703-305-6701; e-mail: gebken.richard@epa.gov) or Bonaventure Akinlosotu at (Phone: 703-605-0653; e-mail: akinlosotu.bonaventure@epa.gov) during the hours of 7:00 am to 4:00 pm EST with a response and for any questions concerning this letter. When submitting information or data in response to this letter, a copy of this letter must accompany the submission to facilitate processing.

Sincerely,



Richard J. Gebken
Product Manager 10
Insecticide Branch
Registration Division (7505P)



Re: EPA Update for product 2596-RAA, 2596-RAG, 2596-RAU, 2596-RAL

RRosenwasser o Wilkinson Unugboji

02/15/2011 11:32 AM

History: This message has been replied to.

Unugboji:

Please find attached the documents you have requested. This should correct all deficiencies noted.

If you have any questions or need additional information, please give me a call or send an email.

Thanks for your help in this matter.

Robert

Robert Rosenwasser
Director, Regulatory Affairs
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094-3688
email: rosenwasser@hartz.com
phone: 201-271-4800, ext. 7202

Unugboji.Wilkinson@epamail.epa.gov

To rosenwasser@hartz.com

02/15/2011 10:50 AM

cc

Subject EPA Update for product 2596-RAA, 2596-RAG, 2596-RAU, 2596-RAL

Hi Mr. Rosenwasser,

Please consider this email as a follow-up to our earlier conversation concerning the deficiencies associated with the application packages being used to support the registration of Hartz Reference #131 (2596-RAA), Hartz Reference #128 (2596-RAG), Hartz Ref #129 (2596-RAU) and Hartz Ref #130 (2596-RAL). Below is the list of deficiencies:

- * The external use data matrix (8570-35) and formulator's exemption statement (8570-27) are missing for all registration packages
- * The method of data support selected on the certification with respect to citation of data (8570-34) for all registration packages is incorrect.

Please email to me the corrections for the deficiencies listed above. If you have any further questions, please feel free to contact me.

Regards,

Unugboji Wilkinson
Data Analyst - MacFadden/EPA Contractor
One Potomac Yard
2777 S.Crystal Drive, S-6921

Arlington, VA 22202
Tel: (703) 347.8518
Fax: (703) 305.5060
EPA mail: unugboji.wilkinson@epa.gov



EPA documents.pdf

R 310

End Use (EP) or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGA).
Must submit Group A and B product chemistry data for each proposed product unless it's a 100% identical (repack): YES or NO (circle one)

Guideline No.	Group A: Product Chemistry Data Study Title	EP Data Submitted		MP Data Submitted		TGA	
		Yes	No	Yes	No	Yes	No
830.1550	Product Identity & Composition	✓					
830.1600	Description of materials used to produce the product	✓					
830.1650	Description of formulation process	✓					
830.1670	Discussion on the formation of impurities	✓					
830.1700	Preliminary analysis		✓				
830.1750	Certified limits (158.345)	✓					
830.1800	Enforcement analytical method	✓					

Guideline No.	Group B: Product Chemistry Data Study Title	EP Data Submitted		MP Data Submitted		TGA	
		Yes	No	Yes	No	Yes	No
830.6302	Color	✓					
830.6303	Physical State	✓					
830.6304	Odor	✓					
830.6313	Stability to normal and elevated temperatures metal and metal ions						
830.6314	Oxidation/Reduction (Chemical incompatibility)		✓				
830.6315	Flammability	✓					
830.6316	Explosibility		✓				
830.6317	Storage stability		✓				
830.6319	Miscibility		✓				
830.6320	Corrosion Characteristics		✓				
830.6321	Dielectric Breakdown Voltage		✓				
830.7000	pH		✓				
830.7050	UV/ Visible Absorption						
830.7100	Viscosity	✓					
830.7200	Melting Point						
830.7220	Boiling Point						
830.7300	Density	✓					
830.7370	Dissociation Constant						
830.7550	Partition Coefficient						
830.7840	Water Solubility						
830.7950	Vapor Pressure						

Grayed out = data not required

R 310

New products must either: 1) supply the product specific acute toxicity 6 pack data (listed below), or 2) provide a bridging rationale document. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Data submitted		Cited	
		Yes	No	Yes	No
870.1100	Acute Oral (LD50)		✓		
870.1200	Acute Dermal (LD50)		✓		
870.1300	Acute Inhalation (LC50)		✓		
870.2400	Acute Eye Irritation		✓		
870.2500	Acute Dermal Irritation		✓		
870.2600	Dermal Sensitization		✓		

Efficacy – which guideline is used depends on the proposed label use

Guideline No.	Study Title	Data submitted		Cited		Comments
		Yes	No	Yes	No	
810.3100	Soil Treatments for Imported Fire Ants		✓			
810.3200	Livestock, Poultry, Fur and Wool-Bearing Animal Treatments					
810.3300	Treatments to Control Pests of Humans and Pets					
810.3400	Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments					
810.3500	Premises Treatments					
810.3600	Structural Treatments					
810.3800	Methods for Efficacy Testing of Termite Baits					



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

February 14, 2011

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

THE HARTZ MOUNTAIN CORP.
ATTN: ROBERT ROSENWASSER
400 PLAZA DRIVE
SECAUCUS, NJ 07094-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 08-FEB-11. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

February 10, 2011

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-445037
EPA File Symbol or Registration Number: 2596-RAA
Product Name: HARTZ REFERENCE #131
EPA Receipt Date: 08-Feb-2011
EPA Company Number: 2596
Company Name: THE HARTZ MOUNTAIN CORP.

THE HARTZ MOUNTAIN CORP.
ATTN: ROBERT ROSENWASSER
400 PLAZA DRIVE
SECAUCUS, NJ 07094-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R310

NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT
CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST EFFICACY);

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee
Ombudsman at (703) 308-9362.

Sincerely, *Teresa Snow*
Front End Processing Staff
Information Technology & Resources Management Division



483792-00

THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094 201/271-4800
REGULATORY AFFAIRS

February 7, 2011

Document Processing Desk (APPL)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: **Mr. Richard Gebken (PM # 10)**
RE: HARTZ REF #128, EPA Reg. No. 2596-RAG
HARTZ REF #129, EPA Reg. No. 2596-RAU
HARTZ REF #130, EPA Reg. No. 2596-RAL
HARTZ REF #131, EPA Reg. No. 2596-RAA

PRIA CODE = R310

Dear Mr. Gebken:

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688 is filing this application to register 4 new products that are based on the Cite-All Method of Support from Merial.

A complete Transmittal Document is attached which states all the documents that are being submitted in support of this registration.

A check for \$19,228 is also enclosed to cover the application fees for the 4 new products and is submitted under PRIA Code R310.

If you have any questions or need any additional information, please feel free to call me at (201) 271-4800, ext. 7202 or <mailto:rosenwasser@hartz.com>.

Sincerely yours,

Robert Rosenwasser
Director, Regulatory Affairs

TRANSMITTAL DOCUMENT

1. NAME AND ADDRESS OF SUBMITTER

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094

2. REGULATORY ACTION IN SUPPORT OF WHICH THESE PACKAGES ARE SUBMITTED

Applications for Registration of 4 new products containing:

Fipronil; Hartz Reference #128, EPA File Symbol 2596-RAG

Fipronil; Hartz Reference #129, EPA File Symbol 2596-RAU

Fipronil and (S)-Methoprene; Hartz Reference #130, EPA File Symbol 2596-RAL

Fipronil and (S)-Methoprene; Hartz Reference #131, EPA File Symbol 2596-RAA

3. TRANSMITTAL DATE February 7, 2011

4. LIST OF SUBMITTED DOCUMENTS

For Reference #128, EPA File Symbol 2596-RAG

VOLUME 1	Product Chemistry Self-Certification	(3 copies)
VOLUME 2	Product Chemistry Product Identity and Composition, Analysis, Certification of Ingredients Manufacturing Process Discussion of Impurities Confidential Statement of Formula	(3 copies)
VOLUME 3	Product Chemistry: Enforcement Analytical Method Method is also applicable to Hartz Reference #129, EPA File Symbol 2596-RAU	(3 copies)

For Reference #129, EPA File Symbol 2596-RAU

VOLUME 1	Product Chemistry Self-Certification,	(3 copies)
VOLUME 2	Product Chemistry Product Identity and Composition, Analysis, Certification of Ingredients Manufacturing Process Discussion of Impurities Confidential Statement of Formula	(3 copies)
VOLUME 3	Product Chemistry: Enforcement Analytical Method	(See above)

For Reference #130, EPA File Symbol 2596-RAL

VOLUME 1	Product Chemistry Self-Certification,	(3 copies)
VOLUME 2	Product Chemistry Product Identity and Composition, Analysis, Certification of Ingredients Manufacturing Process Discussion of Impurities Confidential Statement of Formula	(3 copies)
VOLUME 3	Product Chemistry: Enforcement Analytical Method Method is also applicable to Hartz Reference #131, EPA File Symbol 2596-RAA	(3 copies)

For Reference #131, EPA File Symbol 2596-RAA

1379201 VOLUME 1	Product Chemistry Self-Certification	(3 copies)
379202 VOLUME 2	Product Chemistry Product Identity and Composition, Analysis, Certification of Ingredients Manufacturing Process Discussion of Impurities Confidential Statement of Formula	(3 copies)
VOLUME 3	Product Chemistry: Enforcement Analytical Method	(See above)

For each application, the following documents are submitted:

1. Completed Application Form (8570-1)
2. Data Matrix
3. Certification with Respect to Citation of Data (8570-34)
4. Data Matrix listing company that is utilized in cite-all method.
5. Completed Confidential Statement of Formulas (One loose copy and one copy in Vol. 2 Product Chemistry)
6. Product labels, 6 copies each.
7. Check in the amount of \$19,228 for 4 applications, PRIA Code R310.

5. COMPANY OFFICIAL Robert Rosenwasser, Director, Regulatory Affairs

6. SIGNATURE

7. PHONE 201-271-4800, ext. 7202



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 2596-RAA	2. EPA Product Manager R. Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) HARTZ Reference # 131	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) The Hartz Mountain Corporation 400 Plaza Drive Secaucus, NJ 07094-3688 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

New product registration.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt. 0.50 mL	No. per container 1-150	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 0.50 mL (multiple tubes per package)		5. Location of Label Directions <input checked="" type="checkbox"/> on outer packaging	
6. Manner in Which Label is Affixed to Product label is printed on packaging		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper, glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other: Inner dosage tubes have required text printed on them	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Robert Rosenwasser		Title Director, Regulatory Affairs	
		Telephone No. (Include Area Code) 201-271-4800, ext. 7202	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Director, Regulatory Affairs	
4. Typed Name Robert Rosenwasser		5. Date February 4, 2011	

Hartz

THE HARTZ MOUNTAIN CORPORATION
400 PLAZA DRIVE
SECAUCUS, NJ 07094

No. 289641

FE. 07-FEB-11

VENDOR NAME US ENVIRONMENTAL PROTE VENDOR NO. 1992

INVOICE NO	INVOICE DATE	DESCRIPTION	DISCOUNT AMOUNT	NET AMOUNT
REGISTRATI	01-FEB-11	1000023565 P--	0.00	19,228.00
289641 D			0.00	19,228.00

PLEASE DETACH AND RETAIN THIS STATEMENT AS YOUR RECORD OF PAYMENT. Thank You!

THIS CHECK CONTAINS SAFETY FEATURES FRONT AND BACK. DO NOT CASH UNLESS YOU CAN SEE THE WORD "SAFE" WHEN HOLDING AT AN ANGLE.

Hartz

Bank of America

No. 289641



64-1228
611 GA

THE HARTZ MOUNTAIN CORPORATION
400 PLAZA DRIVE
SECAUCUS, NJ 07094

CHECK DATE 07-FEB-11 CHECK NUMBER 289641 CHECK AMOUNT *****19,228.00

Nineteen Thousand Two Hundred Twenty-Eight Dollars And 00 Cents***

US ENVIRONMENTAL PROTECTION AGENCY
PESTICIDE MAINTENANCE FEES
PO BOX 979031
ST LOUIS, MO 63197-9000

BY

BY

289641



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094, 201-271-4800	EPA Registration Number/File Symbol 2595-RAA
Active Ingredient(s) and/or representative test compound(s) Fipronil, (S)-methoprene	Date February 15, 2011
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 159) Indoor Residential	Product Name Hartz Reference #131

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
--	---

SECTION II: GENERAL OFFER TO PAY

(Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements)

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (1) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (2) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Date

Typed or Printed Name and Title

2/15/2011

Robert Rosenwasser, Director, Regulatory Affairs



United States
Environmental Protection Agency
Washington, DC 20460
Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address The Hartz Mountain Corporation 400 Plaza Drive Secacus, NJ 07094	EPA File Symbol/Registration Number 2596-RAA						
	Product Name Hartz Reference 131						
	Date of Confidential Statement of Formula (EPA Form 8570-4) 02/04/2011						
<p>As an authorized representative of the applicant for registration of the product identified above, I certify that:</p> <p>(1) This product contains the following active ingredient(s):</p> <p style="padding-left: 40px;">Fipronil (S)-Methoprene</p> <p>(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).</p> <p>(3) Indicate by checking (A) or (B) below which paragraph applies:</p> <p><input checked="" type="checkbox"/> (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).</p> <p style="text-align: center;">OR</p> <p><input type="checkbox"/> (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.</p> <p>(4) The following active ingredients in this product qualify for the formulator's exemption.</p>							
Source							
Active Ingredient 5-Amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-4 [(1R,S)-(trifluoromethyl)sulfinyl]-1H-pyrazole-3-carbonitrile CAS# 122068-37-3 (S)-Methoprene CAS # 65733-16-6	<table border="1"> <thead> <tr> <th data-bbox="592 1438 1047 1470">Product Name</th> <th data-bbox="1047 1438 1421 1470">Registration Number</th> </tr> </thead> <tbody> <tr> <td data-bbox="592 1470 1047 1701">[REDACTED]</td> <td data-bbox="1047 1470 1421 1701">[REDACTED]</td> </tr> <tr> <td data-bbox="592 1701 1047 1743">[REDACTED]</td> <td data-bbox="1047 1701 1421 1743">[REDACTED]</td> </tr> </tbody> </table>	Product Name	Registration Number	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Product Name	Registration Number						
[REDACTED]	[REDACTED]						
[REDACTED]	[REDACTED]						
Signature 	<table border="1"> <thead> <tr> <th data-bbox="592 1743 1047 1774">Name and Title</th> <th data-bbox="1047 1743 1421 1774">Date</th> </tr> </thead> <tbody> <tr> <td data-bbox="592 1774 1047 1816">R. Rosenwasser, Dir, Reg. Affairs</td> <td data-bbox="1047 1774 1421 1816">02/15/2011</td> </tr> </tbody> </table>	Name and Title	Date	R. Rosenwasser, Dir, Reg. Affairs	02/15/2011		
Name and Title	Date						
R. Rosenwasser, Dir, Reg. Affairs	02/15/2011						

EPA Form 8570-27 (Rev. 06-2004)

 Copy 1 - EPA
 Copy 2 - Applicant copy

Product ingredient source information may be entitled to confidential treatment



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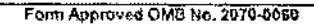
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DATA MATRIX

Date February 4, 2011	EPA Reg. No. 2596-RAA	Page 1 of 2
Applicant's/Registrant's Name & Address: Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094		Product Hartz Reference #131

Ingredient Fipronil, (S)-methoprene

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830-1550	Product identification and composition	submitted	Hartz	Own	
830-1600	Beginning materials	submitted	Hartz	Own	
830-1650	Description of formulation process	submitted	Hartz	Own	
830-1670	Formation of impurities	submitted	Hartz	Own	
830-1750	Certified limits	submitted	Hartz	Own	
830-1800	Enforcement analytical method	submitted	Hartz	Own	
830-6302	Color	submitted	Hartz	Own	Self-certification
830-6303	Physical state	submitted	Hartz	Own	Self-certification
830-6304	Odor	submitted	Hartz	Own	Self-certification
830-6314	Oxidation/Reduction	Waiver	Hartz	Own	Self-certification
830-6315	Flammability	submitted	Hartz	Own	Self-certification
830-6316	Explosibility	Waiver	End use product is not potentially explosive.		
830-6317	Storage stability	To be submitted	Hartz	Own	In progress
830-6319	Miscibility	Waiver	End use product is not to be diluted with petroleum solvents.		
Signature 			Name and Title Robert Rosenwasser Director, Regulatory Affairs		Date February 4, 2011



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Applicant's/Registrant's Name & Address: Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094		Product Hartz Reference #131	

[illegible]

Date
February 4, 2011



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EPA Reg. No. 2596-RAA

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Applicant's/Registrant's Name & Address: Hartz Mountain Corporation, 400 Plaza Dr.,
Secaucus, NJ 07094

Product	Hartz Reference #131
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Ingredient Fipronil, (S)-methoprene


[illegible]



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Date February 15, 2011		EPA Reg. No. 2596-RAA		Page 1 of 2				
Applicant's/Registrant's Name & Address: Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094		Product Hartz Reference #131						
Ingredient Fipronil, (S)-methoprene								
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note			
			Hartz	Own				
			Hartz	Own				
			Hartz	Own				
			Hartz	Own				
			Hartz	Own				
			Hartz	Own				
			Hartz	Own	Self-certification			
			Hartz	Own	Self-certification			
			Hartz	Own	Self-certification			
			Hartz	Own	Self-certification			
			Hartz	Own	Self-certification			
			End use product is not potentially explosive.					
			Hartz	Own	In progress			
End use product is not to be diluted with petroleum solvents.								
Signature 			Name and Title Robert Rosenwasser Director, Regulatory Affairs		Date February 15, 2011			



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Applicant's/Registrant's Name & Address: Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094		Product Hartz Reference #131			
Ingredient Flpronil, (S)-methoprene					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Hartz	Own	In progress
			End use product is not to be used around electrical equipment.		
			End use product is not to be dispersed with water.		
			Hartz	Own	Self-certification
			Hartz	Own	Self-certification
Signature 			Name and Title Robert Rosenwasser Director, Regulatory Affairs		Date February 15, 2011

Confidential Statements of Formula may be entitled to confidential treatment